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EPA SERIES 361

MEMORANDUM

Date: 05-DEC-2007

Subject: PP#: 6F7162. Mesotrione: Section 3 Registration Request for Uses on Asparagus, Grass Grown for Seed, Oats, Okra, Rhubarb, Sugarcane, Grain Sorghum, and Sweet Sorghum. Summary of Analytical Chemistry and Residue Data.

DP#: 338109
PC Code: 122990
40 CFR 180. 571
Chemical Class: Triketone Herbicide (Group 27)

Decision Number: 373106
MRID Nos.: 47013801-47013808

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Executive Summary

Mesotrione is a triketone herbicide which inhibits the enzyme *p*-hydroxyphenyl-pyruvate dioxygenase (HPPD), disrupting carotenoid biosynthesis. This process leads to the destruction of chlorophyll, resulting in a bleaching effect in susceptible plants. Mesotrione is intended for preemergence and postemergence use for the selective control of annual broadleaf weeds. Mesotrione is currently registered for use on field, pop, and sweet corn. A Section 18 Emergency Exemption use has been granted on cranberry (set to expire 31-DEC-2007). A Special Local Need (SLN) use has been approved in Illinois and Minnesota for the oilseed crop, cuphea. A petition (PP#6F7023) is pending for uses on berry group 13, cranberry, flax, and millet, as well as a Section 18 Emergency Exemption use on grain sorghum in Kansas (Reg#: 06KS01).

Syngenta Crop Protection, has submitted a petition, PP#6F7162, for the establishment of permanent tolerances for residues of the herbicide mesotrione (2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione) in/on the following raw agricultural commodities (RACs):

Asparagus	0.01 ppm
Grass, seed screenings	0.10 ppm
Grass, straw	0.10 ppm
Grass, forage	0.01 ppm
Grass, hay	0.01 ppm
Oats, grain	0.01 ppm
Oats, straw	0.01 ppm
Oats, forage	0.01 ppm
Oats, hay	0.01 ppm
Okra	0.01 ppm
Rhubarb	0.01 ppm
Sorghum, forage	0.01 ppm
Sorghum, stover	0.01 ppm
Sorghum, grain	0.01 ppm
Sorghum, sweet	0.01 ppm
Sugarcane	0.01 ppm

Concurrently, Syngenta has proposed to amend the product label for Callisto® Herbicide (EPA Reg. No. 100-1131) to add new uses on asparagus, grass grown for seed, oats, okra, rhubarb, sorghum (grain and sweet), and sugarcane. Callisto® Herbicide is a suspension-concentrate (SC) formulation of mesotrione containing 4 lbs ai/gal. It is proposed for uses on the above-listed crops for preemergence and/or postemergence uses at maximum seasonal rates ranging from 0.094 to 0.334 lbs ai/A with preharvest intervals (PHIs) of 14-114 days.

Tolerances for residues of mesotrione are currently established for field corn forage, grain, and stover, popcorn grain and stover, and sweet corn forage, kernel plus cob with husks removed, and stover. Tolerances for sweet corn forage and stover are established at 0.5 and 1.5 ppm, respectively, and all remaining tolerances are established at 0.01 ppm [40 CFR §180.571(a)]. A Section 18 Emergency Exemption time-limited tolerance, which expires 31-DEC-2007, is established for residues of mesotrione in/on cranberry at 0.01 ppm [40 CFR §180.571(b)].

The nature of the residue in field corn and peanut is adequately understood. A cranberry metabolism study has also been submitted but this study was deemed incomplete because of inadequate radiolabeling of the test substance. The results of plant metabolism studies reflecting application of mesotrione labeled in the phenyl ring indicate that the major metabolic pathway in corn, peanut, and cranberry involves cleavage of the cyclohexanedione ring to yield MNBA (4-methanesulfonyl-2-nitro-benzoic acid), which is further reduced to its amino analog, AMBA (2-amino-4-methanesulfonyl-benzoic acid). Mesotrione may also undergo hydroxylation to form 4-OH-mesotrione. The results of metabolism reflecting application of mesotrione labeled in the cyclohexanedione ring (corn and peanut only) show that cyclohexanedione ring may be degraded to CO_2 which is incorporated into natural products, and the cyclohexanedione ring may be oxidized to form 4-OH-mesotrione which is further metabolized to form multiple metabolites. With the exception of 4-OH-mesotrione, metabolites containing both ring moieties were not characterized in any metabolism study. The requirements for plant metabolism data in three dissimilar crops have not been completely fulfilled.

However, the available corn and peanut metabolism data support the proposed uses on grass grown for seed, oats, sorghum, and sugarcane. Furthermore, since asparagus, okra, and rhubarb are minor crops, HED is willing to translate from the available metabolism data. No new data will be required for purposes of this petition. Therefore, HED concludes that mesotrione *per se* is the residue of concern for tolerance enforcement and risk assessment purposes in asparagus, grass grown for seed, oats, okra, rhubarb, sorghum (grain and sweet), and sugarcane.

The nature of the residue in ruminants and poultry has been adequately defined. The residue of concern in livestock commodities is mesotrione *per se* (HED Metabolism Assessment Review Committee (MARC), 26-SEP-2001). There is no reasonable expectation of quantifiable mesotrione residues of concern in eggs, milk, and the meat, fat, or meat byproducts of poultry and ruminants as a result of the proposed uses [40 CFR Category 180.6(a)(3)]. If in the future, the petitioner proposes a use which increases the dietary burdens, then this conclusion will be re-evaluated.

The nature of the residue in rotational crops is adequately understood. HED previously concluded that for tolerance expression and risk assessment purposes, the residue of concern in/on rotational crop commodities is mesotrione *per se*. The proposed uses are supported by acceptable limited field rotational crop studies from a previous mesotrione petition for field corn uses. Tolerances for inadvertent residues of mesotrione in/on rotational crops are not required, and the proposed rotational crop restrictions are adequate.

A high-performance liquid chromatography (HPLC)/fluorescence detector (FLD) method, Method TMR0882B, is available for the enforcement of tolerances in plant commodities. Liquid chromatography with tandem mass-spectrometry detectors (LC-MS/MS) Method RAM 366/01 is also available for the confirmation of residues of mesotrione and MNBA in plant commodities. Method RAM 366/01 has been forwarded to the U.S. Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual (PAM) Volume II as a confirmatory method. No livestock commodity methods have been submitted, and none are required for the purpose of this petition.

Samples of asparagus, grass seed, straw, forage, and hay, oat forage, hay, straw, and grain, okra,

rhubarb, sorghum forage, stover, grain, and aspirated grain fractions (AGFs), and sugarcane were analyzed for residues of mesotrione *per se* using modified versions of LC-MS/MS method RAM 366/01. The method is adequate for data collection based on acceptable concurrent recovery data for the listed matrices. The validated limit of quantitation (LOQ) was 0.01 ppm.

The requirements for multiresidue method (MRM) data are fulfilled. None of the tested multiresidue methods adequately recovered residues of mesotrione *per se*. The multiresidue methods are, therefore, not adequate for tolerance enforcement.

There are adequate storage stability data for corn matrices, radish root, soybean seed, blueberry, asparagus, sugarcane, and okra to support the storage conditions and durations of RAC samples (asparagus, grass grown for seed, oats, okra, rhubarb, sorghum, and sugarcane) discussed in this petition.

Adequate magnitude of the residue have been submitted and reviewed for the RACs of asparagus, grass grown for seed, oats, okra, rhubarb, sorghum (grain), and sugarcane. The number and locations of field trials that were conducted for these crops are in accordance with OPPTS Guideline 860.1500 and reflect the proposed use patterns.

No processing studies were submitted with this petition. However, the magnitude of the residue studies submitted for oats and sugarcane included data from field trials which reflected exaggerated rate treatments. Residues of mesotrione were below the LOQ (<0.01 ppm) in/on oat grain and sugarcane following treatment(s) at 3x and 5x. Based on these data, HED will not require residue data for the processed commodities of oats (flour and groats/rolled oats) or sugarcane (molasses and refined sugar) at this time. There are no processed commodities for grain sorghum that require tolerances.

Field corn processing data were submitted in conjunction with a previous petition. The processing data indicated that tolerances for residues of mesotrione in the processed commodities of field corn were not required. Based on previously-submitted corn processing data, residues are not expected to concentrate in sweet sorghum syrup; therefore, tolerances are not required.

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) established for residues of mesotrione in/on crop or livestock commodities. Therefore, there are no issues of international harmonization raised by this action.

Regulatory Recommendations and Residue Chemistry Deficiencies

Pending submission of revised Sections B and F, there are no residue chemistry issues that would preclude granting an unconditional registration for the requested uses of mesotrione on asparagus, grass grown for seed, oats, okra, rhubarb, sorghum (grain and sweet), and sugarcane. The proposed uses and the submitted data support the following permanent tolerances for residues of mesotrione *per se* in/on the following RACs:

Asparagus	0.01 ppm
Grass, seed screenings	0.10 ppm
Grass, straw	0.10 ppm
Grass, forage	0.01 ppm
Grass, hay	0.01 ppm
Oat, grain	0.01 ppm
Oat, straw	0.01 ppm
Oat, forage	0.01 ppm
Oat, hay	0.01 ppm
Okra	0.01 ppm
Rhubarb	0.01 ppm
Sorghum, grain, forage	0.01 ppm
Sorghum, grain, stover	0.01 ppm
Sorghum, grain, grain	0.01 ppm
Sorghum, sweet	0.01 ppm
Sugarcane, cane	0.01 ppm

A human-health risk assessment will be prepared in a separate document.

860.1200 Proposed Uses

The submitted proposed label's (4 lbs/gal SC formulation; Callisto® Herbicide; EPA Reg. No. 100-1131) general 'Directions for Use' section states that aerial application is not to be used unless there is valid Supplemental Labeling bearing directions for use for aerial application. The submitted field trial data for this petition did not reflect the use of aerial application, nor was a Supplemental Label submitted to HED for review; therefore, this statement should be removed from the proposed label. Furthermore, the field trials reflect the proposed use pattern, except that a 14-day PGI is proposed for the feeding of forage and hay on the label and the field trials reflect a 74-day PGI. The label should be revised to reflect a 74-day PGI for the feeding of grass forage and hay. Furthermore, there is a proposed 30-day PGI for sweet and grain sorghum. Since a numerical PHI is not required for a pre-emergent/preplant non-incorporated use, this restriction is not practical and should be removed from the label. **A revised Section B should be submitted.**

Background

The chemical structure and nomenclature of mesotrione is presented in Table 1. The physicochemical properties of the technical grade of mesotrione are presented in Table 2.

Table 1. Mesotrione Nomenclature.

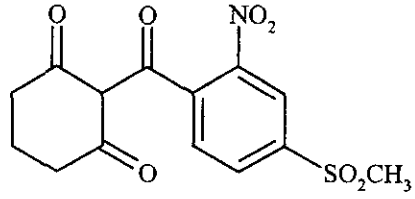
Chemical structure	
Common name	Mesotrione
Company experimental name	ZA1296
IUPAC name	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
CAS name	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
CAS registry number	104206-82-8
End-use product (EP)	4 lbs/gal SC (Callisto® Herbicide; EPA Reg. No. 100-1131)

Table 2. Physicochemical Properties of Mesotrione.

Parameter	Value	Reference
Melting range	148.7-152.5°C	RD Memo, H. Podall, 24-FEB-2000; DP#: 263245
pH	3.4 (1% dispersion in water; 25°C)	
Density	1.46 g/mL, 20°C	
Water solubility	20°C 160 ppm, unbuffered water 0.22 g/100 mL, pH 4.8 1.5 g/100mL, pH 6.9 2.2 g/100 mL, pH 9	
Solvent solubility	20°C 0.37 g/100 mL, methanol 1.7 g/100 mL, ethyl acetate 0.27 g/100 mL, toluene 10.4 g/100 mL, acetonitrile <0.03 g/100 mL, heptane 8.1 g/100 mL, acetone	
Vapor pressure	4.3 x 10^{-8} torr, 20°C	
Dissociation constant, pK_a	3.12, 20°C	
Octanol/water partition coefficient, Log(K_{OW})	20°C log P_{OW} = 0.11 in unbuffered water log P_{OW} = 0.90 in pH 5 buffer log P_{OW} <-1 at pH 7 and 9 buffered water	
UV/visible absorption spectrum	Absorption maximum in methanol at 256 mu, with a molar extinction coefficient of 2.24 x 104 M cm.	

860.1200 Directions for Use

Syngenta has submitted a proposed label for the 4 lbs/gal SC formulation (Callisto® Herbicide; EPA Reg. No. 100-1131). The proposed Section 3 use directions for asparagus, grass grown for seed, oats, okra, rhubarb, sorghum (grain and sweet), and sugarcane are presented in Table 3.

Table 3. Summary of Directions for Use of Mesotrione.

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lbs ai/A)	Max. No. Applic. Per Year	Max. Seasonal Applic. Rate (lbs ai/A)	PHI (days)
Asparagus					
Prior to spear emergence and/or postharvest broadcast or banded	4 lbs ai/gal SC [100-1131]	0.094-0.240	2	0.24	Not specified (NS)
	Use Directions and Limitations: Applications may be made in the spring prior to spear emergence and/or postharvest (after final harvest). Use of crop oil concentrate (COC) at 1% v/v **or** a nonionic surfactant (NIS) at 0.25% v/v is recommended. In addition, a UAN fertilizer at 2.5% v/v **or** ammonium sulfate (AMS) at 8.5 lb/100 gallons of spray solution may be added to improve burndown of existing weeds.				
Grass grown for seed (bluegrass, perennial ryegrass, and tall fescue only)					
Preemergence to newly seeded crop broadcast surface	4 lbs ai/gal SC [100-1131]	0.188	1	0.188	60 for harvest of seed or straw 14 for grazing or feeding forage
Postemergence to emerged grass crop broadcast	4 lbs ai/gal SC [100-1131]	0.094-0.188			
	Use Directions and Limitations: Preemergence application or postemergence application may be made, but not both. For postemergence application, use of COC at 1% v/v **or** a NIS at 0.25% v/v is recommended. In addition, a UAN fertilizer at 2.5% v/v **or** AMS at 8.5 lb/100 gallons of spray solution may be added to improve weed control. Do not apply to seed species not listed on the label.				
Oat					
Preemergence prior to oat emergence broadcast	4 lbs ai/gal SC [100-1131]	0.188	1	0.188	50 for harvest of grain 30 for grazing or feeding forage
Postemergence after oat emergence broadcast	4 lbs ai/gal SC [100-1131]	0.094		0.094	
	Use Directions and Limitations: Preemergence application or postemergence application may be made, but not both. If emerged weeds are present at time of application, use of COC at 1% v/v **or** a NIS at 0.25% v/v is recommended. In addition, a UAN fertilizer at 2.5% v/v **or** AMS at 8.5 lb/100 gallons of spray solution may be added to improve weed control. If the treated oat crop is lost or destroyed, oats may be replanted immediately. If Callisto® was applied to the lost crop, no additional Callisto® can be applied to the replanted oat crop.				
Okra					
Preemergence banded to the row middles	4 lbs ai/gal SC [100-1131]	0.188	1	0.188	28
Postemergence hooded directed	4 lbs ai/gal SC [100-1131]	0.094		0.094	
	Use Directions and Limitations: Application may be made as a preemergence row-middle or a				

Table 3. Summary of Directions for Use of Mesotrione.

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lbs ai/A)	Max. No. Applic. Per Year	Max. Seasonal Applic. Rate (lbs ai/A)	PHI (days)
	hooded postemergence-direct treatment, but not both. For postemergence hooded application, okra should be at least 3" tall at the time of this application. Use of NIS at 0.25% v/v is recommended. If the treated okra crop is lost or destroyed, okra can be replanted only in the soil band that was not treated with Callisto®. Do not apply as a broadcast application.				
Rhubarb					
Preemergence to dormant established rhubarb	4 lbs ai/gal SC [100-1131]	0.188	1	0.188	21
	Use Directions and Limitations: Application may be made to dormant established rhubarb (prior to spring green-up). If weeds are emerged at time of application, use of COC at 1% v/v **or** a NIS at 0.25% v/v is recommended.				
Sorghum (Grain and Sweet)					
Preemergence or preplant Broadcast non-incorporated	4 lbs ai/gal SC [100-1131]	0.188-0.200	NS	0.200	30 for grazing or feeding forage
	Use Directions and Limitations: Application may be made preemergence or preplant non-incorporated up to 21 days before planting. If weeds are emerged at time of application, use of COC at 1% v/v **or** a NIS at 0.25% v/v is recommended. In addition, a UAN fertilizer at 2.5% v/v **or** ammonium sulfate (AMS) at 8.5 lb/100 gallons of spray solution. Do not apply to emerged sorghum, or in the production of forage sorghum, sudangrass, sorghum-sudangrass hybrids, or dual purpose sorghum.				
Sugarcane					
Preemergence after the planting of plant-cane or after harvest of ratoon-cane	4 lbs ai/gal SC [100-1131]	0.188-0.241	2 (per crop cycle)	0.334 (1 preemergence + 1 postemergence)	NS
Postemergence over-the-top or directed	4 lbs ai/gal SC [100-1131]	0.094		0.188 (2 postemergence)	114 for postemergence over-the-top application 100 for postemergence-directed application
	Use Directions and Limitations: If weeds are emerged at time of application, use of COC at 1% v/v **or** a NIS at 0.25% v/v is recommended. In addition, a UAN fertilizer at 2.5% v/v **or** ammonium sulfate (AMS) at 8.5 lb/100 gallons of spray solution. For additional weed control, the product may be tank mixed with atrazine, asulox, and/or Evoke®. If a preemergence application was made earlier in the season, only one postemergence application may be made. If no preemergence application was made earlier in the season, both a postemergence-over-the-top and postemergence-directed application may be made. RTI = 14 days.				

The type of spray equipment and the spray volumes to be used was not specified for any of the crops for which use is proposed under the current action; however, under the general 'Directions for Use' section, the label states that aerial application is not to be used unless there is valid Supplemental Labeling bearing directions for use for aerial application. In addition, under Application Procedures, the label states that postemergence applications using ground equipment

are to be made using spray volumes of 10-30 gallons/Acre (GPA), and pre-emergence applications using ground equipment are to be made using spray volumes of 10-80 GPA using water or liquid fertilizer (excluding suspension fertilizers) as the carrier. Application through any type of irrigation system is prohibited.

The following rotational crop restrictions are specified on the label: Corn (all types) may be replanted immediately. Small grains may be replanted 120 days after application. Soybeans, sorghum, cotton, peanuts, potatoes, sunflowers, canola, tobacco, and alfalfa can be planted back the following season but not less than 10 months after the last application. Sugar beets, peas, dry beans, snap beans, cucurbits, red clover, and all other rotational crops may be replanted 18 months after application.

Conclusions. The proposed label for the 4 lb/gal SC formulation (Callisto® Herbicide; EPA Reg. No. 100-1131) is adequate to allow evaluation of the residue data relative to the proposed uses. However, the submitted field trial data for this petition did not reflect the use of aerial application, nor was a Supplemental Label submitted to HED for review; therefore, this statement should be removed from the proposed label. The field trials reflect the proposed use pattern, except that a 14-day PGI is proposed for the feeding of forage and hay on the label and the field trials reflect a 74-day PGI. The label should be revised to reflect a 74-day PGI for the feeding of grass forage and hay. Furthermore, there is a proposed 30-day PGI for sweet and grain sorghum. Since a numerical PHI is not required for a pre-emergent/preplant non-incorporated use, this restriction is not practical and should be removed from the label. **A revised Section B should be submitted.**

860.1300 Nature of the Residue - Plants

Memo, S. Levy, 02-MAR-2007; DP#: 326898
Memo, W. Cutchin, 12-JAN-2005; DP#: 283827
Memo, S. Levy, 06-JUN-2001; DP#: 245477
Memo, S. Levy, 26-APR-2001; DP#: 274111

No new plant metabolism studies were submitted with the current petition. Field corn and peanut metabolism studies, reflecting labeling in the cyclohexane (CY) and phenyl (PH) rings of mesotrione, were previously submitted. In addition, a cranberry metabolism study, reflecting labeling in the phenyl ring of mesotrione, was previously submitted.

The field corn and peanut studies were deemed acceptable, and the results were shown to be similar. However, the cranberry study was deemed incomplete because metabolism data from CY-labeling were not submitted. Based on the available plant metabolism studies, HED concluded that the requirements for plant metabolism data in three dissimilar crops have not been completely fulfilled, and that additional plant metabolism data may be required to support future uses on additional crops.

The HED MARC previously concluded that the residue of concern in field corn commodities is mesotrione *per se* (DP#: 274111). HED has also determined that mesotrione *per se* is the residue of concern for tolerance enforcement and risk assessment purposes in berries, cranberries, flax, and millet (PP#6F7023).

The results of plant metabolism studies reflecting application of mesotrione labeled in the phenyl ring indicate that the major metabolic pathway in corn, peanut, and cranberry involves cleavage of the cyclohexanedione ring to yield MNBA, which is further reduced to its amino analog, AMBA. Mesotrione may also undergo hydroxylation to form 4-OH-mesotrione. The results of metabolism studies reflecting application of mesotrione labeled in the cyclohexanedione ring (corn and peanut only) show that the cyclohexanedione ring may be degraded to CO_2 which is incorporated into natural products, and the cyclohexanedione ring may be oxidized to form 4-OH-mesotrione which is further metabolized to form multiple metabolites. With the exception of 4-OH-mesotrione, metabolites containing both ring moieties were not characterized in any metabolism study.

Conclusions: The available corn and peanut metabolism data support the proposed uses on grass grown for seed, oats, sorghum, and sugarcane. Furthermore, since asparagus, okra, and rhubarb are minor crops, HED is willing to translate from the available metabolism data. No new data will be required for purposes of this petition. Therefore, HED concludes that mesotrione *per se* is the residue of concern for tolerance enforcement and risk assessment purposes in asparagus, grass grown for seed, oats, okra, rhubarb, sorghum (grain and sweet), and sugarcane.

860.1300 Nature of the Residue - Livestock

Memo, W. Cutchin, 12-JAN-2005; DP#: 283827
Memo, S. Levy, 06-JUN-2001; DP#: 245477
Memo, S. Levy, 26-APR-2001; DP#: 274111

No new livestock metabolism studies were submitted with the current petition. The nature of the residue in ruminants and poultry has been adequately defined based on previously reviewed cattle and hen studies. The residue of concern in livestock commodities is mesotrione *per se* (Memo, S. Levy, 26-APR-2001; DP#: 274111).

860.1340 Residue Analytical Methods

Memo, J. Negron, 17-AUG-2001; DP#: 261112
Memo, S. Levy, 06-JUN-2001; DP#: 245477
Memo, W. Cutchin, 12-JAN-2005; DP#: 283827

Enforcement method: The current enforcement method for plant commodities is an HPLC method with fluorescence detection, Method TMR0882B. This method was reviewed in conjunction with the field corn petition (PP#8F4954) and has undergone adequate petition method validation (PMV) (Memo, J. Negron, 17-AUG-2001; DP# 261112).

An acceptable confirmatory method, LC-MS/MS method, RAM 366/01, was previously submitted and reviewed for the confirmation of residues of mesotrione and MNBA in corn commodities. The method is entitled "Residue Analytical Method for the Determination of Residues of Mesotrione and 4-(Methylsulfonyl)-2-Nitrobenzoic Acid (MNBA) in Crop Samples." The validated LOQ was 0.01 ppm for each analyte in corn commodities. The limits of detection (LODs) were reported to be 0.002 ppm for mesotrione and 0.005 ppm for MNBA.

This method has been forwarded to the U.S. FDA for inclusion in the PAM Volume II as a confirmatory method. Validation by the EPA's Analytical Chemistry Laboratory (ACL) was not required.

Data collection method: Samples of asparagus, grass seed, straw, forage, and hay, oat forage, hay, straw, and grain, okra, rhubarb, sorghum forage, stover, grain, and AGFs, and sugarcane were analyzed for residues of mesotrione *per se* using modified versions of LC-MS/MS method RAM 366/01. The following is a brief description of the method. Homogenized samples were mixed with sodium chloride (10:1, wt:wt) and extracted with acetonitrile:water (1:1, v:v). An aliquot of the extract was diluted with water, and the final volume adjusted with 90% water/methanol for LC-MS/MS analysis. The monitored ion transition was m/z 338 → 291. The validated LOQ was 0.01 ppm. The method is adequate for data collection based on acceptable concurrent recovery data for the listed matrices.

860.1360 Multiresidue Methods

Memo, S. Levy, 16-NOV-1999; DP#: 260570

The petitioner submitted MRM data with a previous petition, which were forwarded to FDA for full evaluation. The FDA PESTDATA database dated 06/05 (PAM Volume I, Appendix I) indicates that mesotrione is not recovered using MRM Sections 302 (Luke Method; Protocol D). No recovery data pertaining to MRM Section 303 (Mills, Onley, and Gaither Method; Protocol E, nonfatty food) or 304 (Mills Method; Protocol F, fatty food) were included. The MRMs are not adequate for enforcement.

860.1380 Storage Stability

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Memo, S. Levy, 02-MAR-2007; DP#: 326898

Syngenta has submitted the results of a storage stability study with mesotrione on blueberry, asparagus, sugarcane, and okra. Untreated samples of each of these crops were composited, ground, and fortified with mesotrione at a nominal fortification level of 1.0 ppm. The fortified samples were placed in frozen storage at approximately -20°C and analyzed at storage intervals of 0, 1, 3, 6 and 13 months. Samples of blueberry, asparagus, sugarcane, and okra were analyzed for residues of mesotrione using the modified LC-MS/MS analytical method RAM 366/01. The LOQ was 0.01 ppm. The storage stability data indicate that residues of mesotrione are stable at approximately -20 °C for at least 13 months in blueberry, asparagus, sugarcane, and okra.

There are additional adequate storage stability data from previous mesotrione tolerance petitions. Mesotrione and its metabolite MNBA were found to be relatively stable under frozen conditions for up to: (i) 42 months in/on field corn forage, fodder, and grain; (ii) 44 months in/on radish root; and (iii) 40 months in/on soybean seed. Mesotrione was also found to be reasonably stable in/on fortified samples of cranberry stored frozen for up to 217 days.

The storage durations and conditions of samples from the crop field trials associated with this petition are presented in Table 4.

Table 4. Summary of Storage Conditions and Durations of Samples from Crop Field Trial Studies.

Matrix	Storage Temperature (°C)	Actual Storage Duration	Interval of Demonstrated Storage Stability
Asparagus	<-15	13 months	Residues of mesotrione are stable at approximately -20 °C for at least 13 months in asparagus.
Grass straw	- 15	90-293 days (3.0-9.6 months)	Residues of mesotrione are relatively stable in/on fortified soybean seed and corn matrices (forage, stover and grain) stored frozen for 40-42 months.
Grass seed screenings		119-293 days (3.9-9.6 months)	
Grass forage		196-236 days (6.4-7.8 months)	
Grass hay		203-301 days (6.7-9.9 months)	
Oat forage	< -15	56-357 days (1.8-11.7 months)	Residues of mesotrione are relatively stable in/on fortified soybean seed and corn matrices (forage, stover and grain) stored frozen for 40-42 months.
Oat hay		56-378 days (1.8-12.4 months)	
Oat straw		32-331 days (1.1-10.9 months)	
Oat grain		32-331 days (1.1-10.9 months)	
Okra	<-15	11–13 months	Residues of mesotrione are stable at approximately -20 °C for at least 13 months in okra.
Rhubarb	<-15	4-5 months	Residues of mesotrione are stable at approximately -20 °C for at least 13 months in asparagus, sugarcane, and okra crops.
Sorghum forage	-15	176-330 days (~6-11 months)	Residues of mesotrione are relatively stable in/on fortified soybean seed and corn matrices (forage, stover and grain) stored frozen for 40-42 months.
Sorghum stover		119-268 days (~4-9 months)	
Sorghum grain		119-268 days (~4-9 months)	
AGFs		235 days (~8 months)	
Sugarcane	<-15	11-13 months	Residues of mesotrione are stable at approximately -20 °C for at least 13 months in sugarcane.

Conclusions. There are adequate storage stability data for corn matrices, radish root, soybean seed, blueberry, asparagus, sugarcane, and okra to support the storage conditions and durations of RAC samples (asparagus, grass grown for seed, oats, okra, rhubarb, sorghum, and sugarcane) discussed in this petition.

860.1480 Meat, Milk, Poultry, and Eggs

Memo, S. Levy, 02-MAR-2007; DP#: 326898
Memo, W. Cutchin, 12-JAN-2005; DP#: 283827
Memo, S. Levy, 26-APR-2001; DP#: 274111

There are several livestock feedstuffs associated with the proposed uses in the current petition. These include grass (forage, hay, and silage), oats (grain, forage, hay, and straw), sorghum (grain, forage, stover, and AGFs), and sugarcane molasses. These proposed new livestock feed items would replace items with higher or equivalent tolerances (*i.e.*, sweet corn stover); therefore, there would be no increase to the reasonably balanced livestock diets (RBDs) for beef/dairy cattle, poultry, or hog.

For the purpose of this petition, HED concludes that the Category 3 situation still applies based on the residue characterization/identification performed in the livestock metabolism studies and the dietary burdens calculated previously. If in the future, the petitioner proposes a use which increases the dietary burdens, then this conclusion will be re-evaluated, and livestock feeding studies may be required.

860.1500 Crop Field Trials

Asparagus
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Syngenta has submitted field trial data for mesotrione on asparagus. Eight field trials (seven harvest and one decline) were conducted during the 2005 growing season in Regions 2 (NC; 1 trial), 5 (MI; 2 trials), 10 (CA; 3 trials), 11 (OR and WA; 2 trials). At each trial location, there was one untreated and 3 treated plots.

The treatment plots were sprayed with Callisto® 4SC using one of the following three regimes: (1) by one time PSS spray at a rate of 0.24 lb ai/A (269 g ai/ha); (2) by a PSS spray at a rate of 0.24 lb ai/A followed by a POT spray at 0.094 lb ai/A (105 g ai/ha); and (3) by one time POT spray at 0.094 lb ai/A. Spray volumes ranged 2-41 GPA (19-383 L/ha). An adjuvant was added to the spray mixture for the second and third treatment regimes.

Samples of mature asparagus were collected from the treated and control plots. Samples treated with Treatment Regimes 2 and 3 were collected at a 2-day PHI. A PHI was not applicable for the preemergence soil surface spray (Regime 1). Samples from one CA trial site (WD-HR-05-6274) were collected at 3 days PHI interval. In addition, at one MI trial site, asparagus samples were harvested at 0, 1, 2, and 3 days after the last application to generate residue decline data.

Asparagus samples were analyzed for residues of mesotrione using a slightly modified version of LC-MS/MS method RAM 366/01; the validated LOQ was 0.01 ppm. The method was adequate for data collection based on acceptable concurrent method recoveries.

Asparagus samples were stored frozen prior to analysis; the maximum storage interval from harvest to extraction was 18 months. The storage conditions and durations of samples are

supported by adequate storage stability data (see Table 4).

A summary of residue data from the asparagus field trials is presented in Table 6. At the proposed use pattern (Treatment Regime 1), residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples which received a single preemergence treatment at 0.24 lb ai/A (1x the maximum proposed seasonal rate). Maximum residues of mesotrione were 0.25 ppm in/on asparagus harvested 2 days after PSS spray application followed by a POT spray for a total rate of 0.334 lb ai/A. Maximum residues of mesotrione were 0.67 ppm in/on asparagus harvested 2 days after POT spray only at a total rate of 0.094 lb ai/A. Residue decline data show that mesotrione residues generally decreased with increasing PHIs. Analysis of untreated control samples demonstrated that they were less then the LOQ (0.01 ppm).

Table 6. Summary of Residue Data from Asparagus Field Trials with Mesotrione.

Commodity	Total Applic. Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels (ppm)*						
			N	Min.	Max.	HAFT[1]	Median	Mean	Std. Dev.
Proposed Use Pattern: Spring application prior to spear emergence at a maximum seasonal rate of 0.24 lb ai/A.									
PSS Treatment									
Asparagus	0.24 – 0.25 [0.266 – 0.275]	NA	16	<0.01	<0.01	<0.01	<0.01	<0.01	NA
PSS + POT Treatment									
Asparagus	0.33 - 0.35 [0.372 – 0.389]	2-3	16	<0.01	0.25	0.23	0.055	0.088	0.075
POT Treatment									
Asparagus	0.092 – 0.97 [0.102 – 0.108]	2-3	16	<0.01	0.67	0.51	0.055	0.115	0.169

[1] HAFT = Highest-Average Field Trial.
*Statistical calculations were performed using a value of 0.01 ppm (LOQ) when residues were reported as <LOQ.

Conclusions: The submitted residue data for asparagus are adequate to fulfill data requirements. The number and locations of crop field trials are in accordance with OPPTS Guideline 860.1500. The field trials (Regime 1; PSS treatment) reflect the proposed use pattern. The available field trial data will support the proposed tolerance for residues of mesotrione in/on asparagus at 0.01 ppm. The tolerance spreadsheet in the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was not utilized for determining an appropriate tolerance level for asparagus because the majority of treated samples bore residues below the LOQ at the proposed application rate.

Grass Grown for Seed
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Syngenta has submitted field trial data for mesotrione on grass grown for seed. Nine field trials were conducted in the U.S. during the 2005 growing season in Regions 5 (KS, MN, and MO; 3 trials), 10 (CA; 1 trial), 11 (ID and WA; 2 trials), and 12 (OR; 3 trials). The grass commodities from one field trial (MN; Zone 5) were lost due to chemical phytotoxicity.

At each trial location, the grass was treated with the Callisto® 4SC formulation using one of the two following treatment regimes: (i) a single postemergence foliar broadcast spray at 0.184-0.192 lb ai/A (Treatment Regime No. 2); or (ii) two postemergence foliar broadcast spray

applications, the first application at ~0.187 lb ai/A followed by a second application at ~0.094 lb ai/A, for a total rate of 0.273-0.287 lb ai/A (Treatment Regime No. 3). An adjuvant (COC) was added to the spray mixture, and applications were made in ~2-30 GPA of water using ground equipment. For Treatment Regime No. 2, a single application was made 60 days prior to harvest of mature seeds and straw, and regrowth of forage and hay were collected 14 days after harvest of mature seeds and straw at a 74-day PHI. For Treatment Regime No. 3, seeds and straw were harvested 30 days after the last application, and regrowth forage and hay were collected 14 days after harvest of mature seeds and straw at a 44-day PHI. Additional samples of regrowth forage and hay were collected at 7, 14, and 21 days after harvest of seed from both treatments to generate residue decline data.

Samples of grass seed, straw, regrowth forage, and regrowth hay were analyzed for residues of mesotrione using LC-MS/MS method RAM 366/01 with a validated LOQ of 0.01 ppm. The method is adequate for data collection based on acceptable concurrent recovery data.

The maximum storage duration of grass samples, from harvest to analysis, was 301 days (~10 months). The storage conditions and durations of samples are supported by adequate storage stability data (see Table 4).

A summary of residue data from the grass field trials is presented in Table 7. At the proposed use pattern (Treatment Regime No. 2), maximum residues of mesotrione were 0.09 ppm in/on samples of grass straw and seed screenings harvested 60 days following a single postemergence foliar broadcast application of the 4 lb/gal SC formulation at 0.184-0.192 lb ai/A (~1x the proposed maximum seasonal rate). Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of grass forage and hay harvested 74 days following Treatment Regime No. 2.

Table 7. Summary of Residue Data from Grass Grown for Seed Crop Field Trials with Mesotrione.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)*						
			N	Min.	Max.	HAFT[1]	Median	Mean	Std. Dev.
Proposed Use Pattern: One preemergence or postemergence application may be made, but not both, at a maximum rate of 0.188 lb ai/A. The proposed PHI is 60 days for seed and straw. A 14-day PGI is proposed for the feeding of forage.									
Treatment Regime No. 2: Single postemergence foliar broadcast application of the 4 lb/gal SC formulation									
Grass straw	0.184-0.192	60	16	<0.01	0.09	0.07	0.01	0.01	0.02
Grass seed screenings	0.184-0.192	60	16	<0.01	0.09	0.09	0.01	0.02	0.03
Grass forage	0.184-0.192	74	14	<0.01	<0.01	<0.01	<0.01	<0.01	--
Grass hay	0.184-0.192	74	14	<0.01	<0.01	<0.01	<0.01	<0.01	--
Treatment Regime No. 3: Two postemergence foliar broadcast spray applications of the 4 lb/gal SC formulation									
Grass straw	0.273-0.287	30	16	<0.01	3.30	2.95	0.03	0.43	1.00
Grass seed screenings	0.273-0.287	30	16	<0.01	2.70	2.55	0.04	0.45	0.86
Grass forage	0.273-0.287	44	14	<0.01	0.01	0.01	<0.01	<0.01	--
Grass hay	0.273-0.287	44	14	<0.01	0.01	0.01	<0.01	<0.01	--

[1] HAFT = Highest-Average Field Trial.
*Statistical calculations were performed using a value of 0.01 ppm (LOQ) when residues were reported as <LOQ.

Maximum residues of mesotrione were 3.30 ppm in/on samples of grass straw and 2.70 ppm

in/on samples of seed screenings harvested 30 days following the last of two postemergence foliar broadcast applications of the 4 lb/gal SC formulation at a total rate of 0.273-0.287 lb ai/A (Treatment Regime No. 3). Residues of mesotrione were at or below the LOQ (<0.01 ppm) in/on all samples of grass forage and hay harvested 44 days following Treatment Regime No. 3.

In the residue decline studies, following Treatment Regime No. 2, residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of regrowth forage and hay. Following Treatment Regime No. 3, low quantifiable residues of mesotrione were observed at the 37-day PHI in samples of regrowth forage (0.01 ppm) and hay (0.02 ppm), but residues declined to below the LOQ (<0.01 ppm) by the 51-day PHI.

Conclusions: The submitted residue data for grass grown for seed are adequate to fulfill data requirements. The number and locations of crop field trials are in accordance with "Grasses Grown for Seed Draft Guidance" (30-SEP-2000). The field trials reflect the proposed use pattern, except that a 14-day PGI is proposed for the feeding of forage and hay on the label and the field trials reflect a 74-day PGI. The label should be revised to reflect a 74-day PGI for the feeding of grass forage and hay. The available field trial data will support the proposed tolerance for residues of mesotrione in/on grass, seed screenings at 0.10 ppm; grass, straw at 0.10 ppm; grass, forage at 0.01 ppm; and grass, hay at 0.01 ppm. The tolerance spreadsheet in the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was not utilized for determining an appropriate tolerance level for grass grown for seed because the majority of treated samples bore residues below the LOQ at the proposed application rate.

Oats, forage, hay, grain, and straw
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Syngenta has submitted field trial data for mesotrione on oats. Sixteen field trials were conducted in the U.S. during the 2005 growing season in Regions 1 (NY; 1 trial), 2 (VA; 1 trial), 5 (IA, IL, KS, MI, MN, ND, NE, SD, and WI; 9 trials), 6 (TX; 1 trial), 7 (NE, ND, and SD; 3 trials), and 8 (KS; 1 trial). At each trial location, oats were treated with the 4 lb/gal SC formulation using one of the following two treatment regimes: (i) a single PSS spray at 0.188 lb ai/A (Treatment Regime No. 2); or (ii) a single POT spray applications at 0.094 lb ai/A with the addition of 0.25% (v:v) NIS (Treatment Regime No. 3).

PHIs were not applicable for trials treated PSS at planting. Oat forage and hay samples were collected 30 days after the POT application, straw and grain were collected 50 days after application. Additional samples of oat forage and hay were collected at 16, 23, 30, and 37 days after POT to generate residue decline data. At one trial, a single POT application of 4 lb/gal SC was applied to oats at exaggerated rates (3x and 5x) for a processing study.

Samples of oat forage, hay, straw, and grain were analyzed for residues of mesotrione using LC-MS/MS method RAM 366/01 with a validated LOQ of 0.01 ppm. The method is adequate for data collection based on acceptable concurrent recovery data.

The maximum storage duration of oat samples, from harvest to analysis, was 378 days (12.4 months). The storage conditions and durations of samples are supported by adequate storage stability data (see Table 4).

A summary of residue data from the oat field trials is presented in Table 8. The two treatment regimes used in the trials reflect the proposed use patterns. Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of oat forage, hay, straw, and grain following either a single PSS application of the 4 lb/gal SC formulation made at planting at 0.188 lb ai/A or a single POT spray at 0.094 lb ai/A.

Table 8. Summary of Residue Data from Oat Field Trials with Mesotrione.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)*						
			n	Min.	Max.	HAFT[1]	Median	Mean	Std. Dev.
***Proposed Use Pattern:* PSS or POT application may be made, but not both. The proposed maximum seasonal rates are 0.188 lb ai/A for PSS treatment and 0.094 lb ai/A for POT treatment. The proposed PHIs are 50 days for grain and 30 days for forage.**									
Treatment Regime No. 2: Single PSS spray made at planting									
Oat forage	0.188	NA	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat hay		NA	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat straw		NA	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat grain		NA	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Treatment Regime No. 3: Single POT spray									
Oat forage	0.094	30	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat hay		30	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat straw		50	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat grain		50	32	<0.01	<0.01	<0.01	<0.01	<0.01	--

[1] HAFT = Highest-Average Field Trial.

*Statistical calculations were performed using a value of 0.01 ppm (LOQ) when residues were reported as <LOQ.

In the residue decline study, residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of oat forage, hay, straw, and grain. Since residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of oat treated at an exaggerated rate (3x and 5x), processing samples were not analyzed.

Conclusions: The submitted residue data for oats are adequate to fulfill data requirements. The number and locations of crop field trials are in accordance with OPPTS Guideline 860.1500. The field trials reflect the proposed use pattern. The available field trial data will support the proposed tolerances for residues of mesotrione in/on oat, grain at 0.01 ppm; oat, straw at 0.01 ppm; oat, forage at 0.01 ppm; and oat hay at 0.01 ppm. The tolerance spreadsheet in the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was not utilized for determining an appropriate tolerance level for oats because the majority of treated samples bore residues below the LOQ.

Okra

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Syngenta has submitted field trial data for mesotrione on okra. Five field trials (four harvest and one decline) were conducted during the 2005 growing season in the U.S. The locations of the okra trials were in Zones 2 (NC; 1 trial), 3 (FL; 1 trial), 4 (MS; 1 trial), and 6 (OK and TX; 2 trials). At each trial location, there was one untreated and five treated plots.

The treated plots were treated with Callisto® 4SC, a formulation of mesotrione, using one of the

five following treatment regimes: (1) PSS spray at a rate of 0.196-0.205 lb ai/A (0.22-0.23 kg ai/ha); (2) PSS spray followed by a POT spray for a total rate of 0.285-0.301 lb ai/A (0.32-0.38 kg ai/ha); (3) PSS spray followed by a postemergence direct (PD) application for a total rate of 0.293-0.300 lb ai/A (0.33-0.34 kg ai/ha); (4) POT spray at 0.093-0.097 lb ai/A (0.105-0.109 kg ai/ha); and (5) PD application at 0.086-0.096 lb ai/A (0.097-0.107 kg ai/ha). Total treatment regime volumes ranged from 4-50 GPA (37-466 L/ha). An adjuvant (0.25% (v:v) NIS) was added to the spray mixture for treatment regimes 2 through 5.

For each of the field trials, one untreated and two treated mature okra pods RAC samples were collected after each of the various spraying regimes. For treatment regimes including POT treatment, samples were collected at a 45 day PHI. For treatment regimes including PD application, samples were collected at a 28 day PHI. It should be noted that the PHIs were considered not applicable for those treated by PSS only. In the decline trial (SA-HR-05-6263), okra pods were collected at 0, 15, 30, 45 and 52 days for samples incorporating treatment by POT spray, and 0, 14, 21, 28, and 35 days for samples incorporating treatment by PD application.

The collected samples of okra were analyzed for residues of mesotrione using a slightly modified version of LC-MS/MS Method RAM 366/01 with a validated LOQ of 0.01 ppm. The method was adequate for data collection based on acceptable concurrent method recoveries.

Okra samples were stored frozen prior to analysis. Maximum storage interval from harvest to extraction was 13 months. The storage conditions and durations of samples are supported by adequate storage stability data (see Table 4).

A summary of residue data from the okra field trials is presented in Table 9. Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of okra harvested from all treatment regimes. In the decline trial, all residues were <0.01 ppm, except for samples harvested at Day 0 for the SS+POT treatment regime (0.09 and 0.2 ppm) and the POT only treatment regime (0.19 and 0.16 ppm). Residue decline data showed that mesotrione residues generally decrease with increasing PHIs.

Table 9. Summary of Residue Data from Okra Field Trials with Mesotrione.

Matrix	Total Applic. Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels (ppm)*						
			N	Min.	Max.	HAFT[1]	Median	Mean	Std. Dev.
Proposed Use Pattern: Preemergence or postemergence application may be made, but not both. The proposed maximum seasonal rates are 0.188 lb ai/A for preemergence treatment and 0.094 lb ai/A for postemergence treatment. The proposed PHI is 28 days.									
PSS Treatment									
Okra	0.196 – 0.205 [0.22 – 0.23]	NA	10	<0.01	<0.01	<0.01	<0.01	<0.01	--
PSS + POT Treatment									
Okra	0.285 - 0.301 [0.32 - 0.38]	45	10	<0.01	<0.01	<0.01	<0.01	<0.01	--
PSS + PD Treatment									
Okra	0.293 – 0.300 [0.33 – 0.34]	28	10	<0.01	<0.01	<0.01	<0.01	<0.01	--
POT Treatment									
Okra	0.093 – 0.097 [0.105 – 0.109]	45	10	<0.01	<0.01	<0.01	<0.01	<0.01	--
PD Treatment									

Okra	0.086 – 0.096 [0.097 – 0.107]	28	10	<0.01	<0.01	<0.01	<0.01	<0.01	--

[1] HAFT = Highest-Average Field Trial.
*Statistical calculations were performed using a value of 0.01 ppm (LOQ) when residues were reported as <LOQ.

Conclusions: The submitted residue data for okra are adequate to fulfill data requirements. The number and locations of crop field trials are in accordance with OPPTS Guideline 860.1500. The field trials reflect the proposed use pattern. The available field trial data will support the proposed tolerance for residues of mesotrione in/on okra at 0.01 ppm. The tolerance spreadsheet in the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was not utilized for determining an appropriate tolerance level for okra because the majority of treated samples bore residues below the LOQ.

Rhubarb
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Syngenta has submitted field trial data for mesotrione on rhubarb. Four supervised field trials (three harvest and one decline) were conducted during the 2006 growing season in the U.S. The locations of the rhubarb trials were in Zones 5 (IL and MI; 2 trials) and 12 (OR and WA; 2 trials). At each trial location, there was one untreated and two treated plots.

The treated plots were sprayed with Callisto® 4SC using one of the following two regimes: by one time PSS spray at a rate of (1) 0.180-0.194 lb ai/A (~211 g ai/ha) or (2) 0.301-0.313 lb ai/A (~336 g ai/ha). Applications were made using a backpack sprayer at a volume of 16.5-30.3 GPA (154-284 L/ha). An adjuvant was not added to the spray formulations.

Samples of mature rhubarb were collected from each trial site at a 42-day PHI. In addition, at the IL site, samples were harvested 28, 35, 42, and 49 days after treatment to generate residue decline data.

The collected rhubarb samples were analyzed for residues of mesotrione using a slightly modified version of LC-MS/MS Method RAM 366/01, with a validated LOQ of 0.01 ppm. The method was adequate for data collection based on acceptable concurrent method recoveries.

Rhubarb samples were stored frozen prior to analysis; the maximum sample storage duration from harvest to extraction was 5 months. The storage condition and duration of samples are supported by adequate storage stability data (see Table 4).

A summary of residue data from the rhubarb field trials is presented in Table 10. Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of rhubarb treated with preemergence spray of Callisto® Herbicide at application rates of ~0.188 and ~0.3 lb ai/A (1.0 and 1.6x the maximum proposed seasonal rate). All but one sample of the residue decline data were below the LOQ (<0.01 ppm). The measurable sample (0.011 ppm) occurred at the 28-day PHI with the ~0.3 lb ai/A application rate.

Table 10. Summary of Residue Data from Rhubarb Field Trials with Mesotrione.									
Matrix	Total Application Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)*						
			N	Min.	Max.	HAFT[1]	Median	Mean	Std. Dev.
Proposed Use Pattern: One preemergence treatment at a maximum seasonal rate of 0.188 lb ai/A with a proposed PHI of 21 days.									
Rhubarb	0.180 – 0.194	42	8	<0.01	<0.01	<0.01	<0.01	<0.01	--
Rhubarb	0.301 – 0.313	42	8	<0.01	<0.01	<0.01	<0.01	<0.01	--

[1] HAFT – Highest-Average Field Trial.
*Statistical calculations were performed using a value of 0.01 ppm (LOQ) when residues were reported as <LOQ.

Conclusions: The submitted residue data for rhubarb are adequate to fulfill data requirements. The number and locations of crop field trials are in accordance with OPPTS Guideline 860.1500. The field trials reflect the proposed use pattern. The available field trial data will support the proposed tolerance for residues of mesotrione in/on rhubarb at 0.01 ppm.

HED notes that the proposed PHI is 21 days, and the submitted data reflect a PHI of 42 days. However, as the proposed use pattern is preemergence and residues were below the LOQ after preemergence treatment at slightly exaggerated rate (1.6x), HED is not requesting the petitioner to amend the label to reflect a 42-day PHI. The tolerance spreadsheet in the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was not utilized for determining an appropriate tolerance level for rhubarb because the majority of treated samples bore residues below the LOQ.

Grain Sorghum
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Syngenta has submitted field trial data for mesotrione on grain sorghum. Twelve field trials were conducted in the U.S. during the 2005 growing season in Zones 2 (SC; 1 trial), 4 (LA; 1 trial), 5 (KS, MO, NE, and SD; 4 trials), 6 (OK and TX; 2 trials), 7 (NE; 1 trial), and 8 (CO, NM, and TX; 3 trials).

At each trial location, sorghum was treated with the 4 lb/gal flowable concentrate (FlC) formulation at 0.2 lb ai/A using a combination of one or more of the following three treatment regimes: (i) a single soil-surface (SS) spray application made at planting (Treatment Regime No. 2); (ii) a single preplant incorporated (PPI) spray applications made at planting (Treatment Regime No. 3); and/or (iii) a single POT spray with the addition of 0.25% (v:v) nonionic surfactant (NIS) at 12" plant height (Treatment Regime No. 4). Applications were made in ~14-21 GPA of water using ground equipment, except for one trial (SC) where applications were made in ~4-5 GPA of water, to simulate an aerial application rate.

Sorghum forage samples were collected 30 days after the POT application; stover and grain samples were collected at maturity. PHIs were not applicable for trials treated by SS spray or PPI at planting. Stover and grain samples were collected at maturity. Additional samples of forage were collected at 0, 9, 16, and 30 days after POT, stover and grain samples were collected 7 days prior to maturity (7P), at maturity, and 7 days after maturity (7A) to generate residue decline data. At two trials, grain samples were processed to generate AGFs.

Samples of sorghum forage, stover, grain, and AGFs were analyzed for residues of mesotrione using LC-MS/MS method RAM 366/01. The method is adequate for data collection based on acceptable concurrent recovery data. The validated LOQ was 0.01 ppm for mesotrione in/on sorghum commodities.

The maximum storage duration of sorghum samples, from harvest to analysis, was 330 days (~11 months). The storage condition and duration of samples are supported by adequate storage stability data (see Table 4).

A summary of residue data from the sorghum field trials is presented in Table 11. Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of sorghum forage, stover, and grain following either a single SS or PPI application of the 4 lb/gal SC formulation made at planting at 0.2 lb ai/A (1x the proposed maximum seasonal rate). The proposed use pattern is represented by Treatment Regime Nos. 2 and 3.

Table 11. Summary of Residue Data from Sorghum Field Trials with Mesotrione.

Commodity	Total Applic. Rate (lb ai/A)	PHI[1] (days)	Residue Levels (ppm)*						
			N	Min.	Max.	HAFT[2]	Median	Mean	Std. Dev.
Proposed Use Pattern: One preemergence or preplant application at a maximum seasonal rate of 0.2 lb ai/A.									
Treatment Regime No. 2: Single SS spray made at planting									
Sorghum, forage	0.2	NA	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Sorghum, stover	0.2	Maturity	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Sorghum, grain	0.2	Maturity	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Treatment Regime No. 3: Single PPI made at planting									
Sorghum, forage	0.2	NA	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Sorghum, stover	0.2	Maturity	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Sorghum, grain	0.2	Maturity	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Treatment Regime No. 4: Single POT									
Sorghum, forage	0.2	30	24	<0.01	0.02	0.02	<0.01	<0.01	0.002
Sorghum, stover	0.2	Maturity	24	<0.01	<0.01	<0.01	<0.01	<0.01	--
Sorghum, grain	0.2	Maturity	24	<0.01	<0.01	<0.01	<0.01	<0.01	--
AGFs	0.2	Maturity	2	<0.01	<0.01	<0.01	<0.01	<0.01	--

[1] PHIs were NA for trials treated by SS spray or PPI at planting. Stover and grain samples were collected at maturity.
[2] HAFT = Highest-Average Field Trial.
*Statistical calculations were performed using a value of 0.01 ppm (LOQ) when residues were reported as <LOQ.

Maximum residues of mesotrione were 0.02 ppm in/on samples of sorghum forage harvested 30 days following a single POT application of the 4 lb/gal SC formulation at 0.2 lb ai/A (Treatment Regime No. 4). No residues of mesotrione were found in any of the sorghum stover, grain, or AGF samples harvested at maturity following Treatment Regime No. 4.

In the residue decline trials, detectable residues of mesotrione were found in 0-day sorghum forage samples and declined to below the LOQ (<0.01 ppm) by the 9-day PHI and remained below the LOQ at the 30-day PHI. Residues were below the LOQ (<0.01 ppm) in/on all samples of sorghum stover and grain collected at all sampling intervals.

Conclusions: The submitted residue data for grain sorghum are adequate to fulfill data requirements. The number and locations of crop field trials are in accordance with OPPTS Guideline 860.1500. The field trials reflect the proposed use pattern (Treatment Regime Nos. 2 and 3; SS at planting or PPI). As per Table 1 of OPPTS 860.1000, sweet sorghum commodities (*i.e.*, seed and forage) will be covered by the sorghum grain commodities; therefore, separate residue data are not needed for sweet sorghum. The available field trial data will support the proposed tolerances for residues of mesotrione in/on sorghum, forage at 0.01 ppm; sorghum, stover at 0.01 ppm; sorghum, grain at 0.01 ppm; and sorghum, sweet at 0.01 ppm.

Data for the AGFs of sorghum are not required for the purpose of this petition considering the proposed use pattern of mesotrione on sorghum is for preemergence or preplant, and residues were below the LOQ (<0.01 ppm) in/on grains following preemergence or postemergence treatment at 1x. The tolerance spreadsheet in the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was not utilized for determining an appropriate tolerance level for sorghum because the majority of treated samples bore residues below the LOQ.

Sugarcane
47013805.der.doc

Syngenta Crop Protection, Inc. has submitted field trial data for mesotrione in/on sugarcane. Eight field trials (six harvest and two decline) were conducted in the U.S. encompassing Regions 3 (3 trials in FL), 4 (3 trials in LA), 6 (1 trial in TX), and 13 (1 trial in HI) during the 2005 growing season. At each trial location, there was one untreated and five treated plots.

The treated plots were treated with Callisto® 4SC, a 4 lb/gal SC formulation of mesotrione, using one of the following three treatment regimes: (1) PSS spray followed by a POT broadcasting spray for a total rate of 0.318-0.360 lb ai/A (0.372-0.403 kg ai/ha); (2) PSS spray followed by a PD application for a total of 0.325-0.348 lb ai/A (0.364-0.389 kg ai/ha); and, (3) POT broadcasting spray followed by a PD application for a total of 0.184-0.202 lb ai/A (0.206-0.226 kg ai/ha). Additionally, sugarcane was treated at exaggerated rates (3x and 5x) by one-time POT spray followed by one-time PD spray at two field trial sites (VN-HR-05-6241 and SD-HR-05-6244), for a processing study. Total treatment regime volumes ranged from 4-51 GPA (39-476 L/ha). An adjuvant (COC) was added to the tank mixtures for POT and PD applications.

For each of the field trials, one untreated and two treated mature sugarcane RAC samples were collected after each of the various spraying regimes. Sugarcane samples were harvested at 114 days after the last application for PSS+POT treatment and at 100 days after the last application for PSS+PD and POT+PD treatments. In the decline trials, sugarcane samples were collected 0, 30, 60, 114 and 121 days after PSS+POT treatment, and 0, 30, 60, 100, and 107 days after PSS+PD or POT+PD treatment.

Samples of sugarcane were analyzed for residues of mesotrione using a slightly modified version of LC-MS/MS method RAM 366/01. The method is adequate for data collection based on

acceptable concurrent recovery data. The validated LOQ was 0.01 ppm for mesotrione in/on sugarcane.

Sugarcane samples were stored frozen prior to analysis; the maximum storage interval from harvest to extraction was 13 months. The storage condition and duration of samples are supported by adequate storage stability data (see Table 4).

A summary of residue data from the sugarcane field trials is presented in Table 12. Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of sugarcane harvested from all treatment regimes.

Table 12. Summary of Residue Data from Sugarcane Field Trials with Mesotrione.

Matrix	Total Applic. Rate (lb ai/A) [kg/ha]	PHI (days)	Residue Levels (ppm)*						
			N	Min.	Max.	HAFT[1]	Median	Mean	Std. Dev.
Proposed Use Pattern: One preemergence treatment and one postemergence treatment for a maximum rate of 0.334 lb ai/A OR two postemergence treatments at a maximum rate of 0.188 lb ai/A. The proposed PHIs when applied postemergence are 114 days for postemergence over the-top application and 100 days for *postemergence directed application.*									
PSS + POT Treatment									
Sugarcane	0.318 – 0.360 [0.372 – 0.403]	114	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
PSS + PD Treatment									
Sugarcane	0.325 – 0.348 [0.364 – 0.389]	100	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
POT + PD Treatment									
Sugarcane	0.184 – 0.202 [0.206 – 0.226]	100	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
POT + PD Treatment, 3x									
Sugarcane	0.589 [0.659]	100	2	<0.01	<0.01	<0.01	<0.01	<0.01	--
POT + PD Treatment, 5x									
Sugarcane	0.932 – 0.985 [1.04 – 1.10]	100	4	<0.01	<0.01	<0.01	<0.01	<0.01	--

[1] HAFT = Highest-Average Field Trial.

*Statistical calculations were performed using a value of 0.01 ppm (LOQ) when residues were reported as <LOQ.

For the two decline trials, residues of mesotrione ranged from <0.01 to 5.75 ppm with measurable residues occurring only from samples harvested at Day 0. Overall, the decline data showed that mesotrione residues decreased with increasing PHIs Samples treated at exaggerated rates (3x and 5x) bore residues below the LOQ (<0.01 ppm). It is noted that additional samples were collected for processing of sugarcane (refined sugar and molasses), but the processed samples were not analyzed because the residues in the RAC from the exaggerated applications were <0.01 ppm.

Conclusions: The submitted residue data for sugarcane are adequate to fulfill data requirements. The number and locations of crop field trials are in accordance with OPPTS Guideline 860.1500. The field trials reflect the proposed use pattern. The available field trial data will support the proposed tolerance of 0.01 ppm for residues of mesotrione in/on sugarcane. The tolerance spreadsheet in the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was not utilized for determining an appropriate tolerance level for sugarcane because the majority of treated samples bore residues below the LOQ.

860.1520 Processed Food and Feed

No conventional processing studies were submitted with this petition. However, the magnitude of the residue studies submitted for oats (47013806.der) and sugarcane (47013805.der) included data from field trials which reflected exaggerated rate treatments. Residues of mesotrione were below the LOQ (<0.01 ppm) in/on oat grain and sugarcane following treatment at 3x and 5x. Based on these data, HED will not require residue data for the processed commodities of oats (flour and groats/rolled oats) or sugarcane (molasses and refined sugar) at this time. There are no processed commodities for grain sorghum that require tolerances.

In a previous review (Memo, S. Levy, 06-JUN-2001; DP#: 245477), field corn processing data were submitted and the data indicated that residues of mesotrione and its metabolite MNBA were each below the analytical method's LOQ (<0.01 ppm) in/on samples of the RAC, field corn grain, harvested 107 days following two broadcast applications of the 4 lb/gal SC formulation at 1.5 lb ai/A/application applied at planting followed by a second postemergence application at 1.0 lb ai/A/application. The total application rate was 2.50 lb ai/A (~5.8x the maximum registered seasonal rate). Mesotrione and MNBA residues were each below the LOQ in the dry milled fractions (corn grits, meal, flour, and crude and refined oil) and the wet milled fractions (corn starch and crude and refined oil) processed from field corn grain bearing non-quantifiable residues. Based on the results of the processing study, tolerances for residues of mesotrione and MNBA in the processed commodities of field corn were not required. Based on the corn processing data, residues are not expected to concentrate in sweet sorghum syrup; therefore, tolerances are not required.

860.1650 Submittal of Analytical Reference Standards

Analytical standards for mesotrione and one metabolite are currently available in the EPA National Pesticide Standards Repository (personal communication with Theresa Cole, ACL/BEAD, 13-JUN-2007).

860.1850 Confined Accumulation in Rotational Crops

Memo, S. Levy, 26-APR-2001; DP#: 274111
Memo, S. Levy, 06-JUN-2001; DP#: 245477

No new confined rotational crop studies were submitted with this petition. An adequate confined rotational crop study was submitted under the previous petition (PP#8F4954) for field corn uses (Memo, S. Levy, 06-JUN-2001; DP#: 245477). TRR expressed as [^{14}C]mesotrione equivalents, accumulated at levels ≥0.01 ppm in the following rotational crop commodities of soybeans and wheat planted in sandy loam soil 30 DAT with uniformly ring-labeled phenyl (PH) or cyclohexane-labeled (CY) [^{14}C]mesotrione at 0.274 lb ai/A (~0.8x maximum proposed seasonal rate to sugarcane): soybean forage, hay, and soybeans, and wheat forage, hay, straw, and grain. TRR in PH samples ranged from 0.038 ppm in wheat grain to 2.58 ppm in wheat straw; in CY samples TRR were lower, ranging from 0.010 ppm in wheat grain to 0.059 ppm in wheat straw.

Based on the components identified, the results of the confined rotational crop study suggest that mesotrione is metabolized in rotational crops via a route similar to that demonstrated in primary crops. HED previously concluded that for tolerance expression and risk assessment purposes, the residue of concern in/on rotational crop commodities is mesotrione *per se* (Memo, S. Levy, 26-APR-2001; DP#: 2741411).

860.1900 Field Accumulation in Rotational Crops

Memo, S. Levy, 06-JUN-2001; DP#: 245477

No new field rotational crop data were submitted with this petition. An acceptable limited field rotational crop study was submitted under the previous petition (PP#8F4954) for field corn uses. Residues of mesotrione and its metabolite MNBA were each less than the method LOQ (<0.01 ppm) in/on all rotational crop matrices (radish roots and tops; soybean forage, hay, and seed; millet forage, hay, straw, and grain; and sorghum forage) from the 29- to 30-day PBI following a single preplant incorporated application made to the primary crop, field corn, of the 4 lb/gal SC formulation at 0.30 lb ai/A/application (~0.9x maximum proposed seasonal rate to sugarcane). Residues of mesotrione and its metabolite MNBA were each less than the method LOQ (<0.01 ppm) in/on all rotational crop matrices (radish roots and tops; endive leaves; and wheat forage, hay, straw, and grain) from the 74- to 100-day PBI following two applications (preplant incorporated and postemergence) made to the primary crop, field corn, of the 4 lb/gal SC formulation at a total rate of 0.50 lb ai/A (~1.5x maximum proposed seasonal rate).

The available field rotational crop data support the proposed PBIs listed on the product label for Callisto® Herbicide: (i) 120 days for small grains; (ii) 10 months for soybeans, sorghum, cotton, peanuts, potatoes, sunflowers, canola, tobacco, and alfalfa; and (iii) 18 months for sugar beets, peas, dry beans, snap beans, cucurbits, red clover, and all other rotational crops.

860.1550 Proposed Tolerances

In the current petition, the proposed tolerance expression is in terms of residues of the herbicide mesotrione (2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione). The HED MARC previously concluded that the residue of concern in field corn commodities is mesotrione *per se* (Memo, S. Levy, 26-APR-2001; DP#: 274111). HED has also determined that mesotrione *per se* is the residue of concern for tolerance enforcement and risk assessment purposes in berries, cranberries, flax, and millet (Memo, S. Levy, 02-MAR-2007; DP#: 326898). The proposed tolerance expression in this petition is consistent with the mesotrione tolerances established in 40 CFR §180.571.

Adequate field trial data are available for the RACs of asparagus, grass grown for seed, oats, okra, rhubarb, sorghum (grain), and sugarcane. As per Table 1 of OPPTS 860.1000, sweet sorghum commodity data (*i.e.*, seed and forage) are covered by the sorghum grain commodities; therefore, separate residue data are not needed for sweet sorghum.

The tolerance spreadsheet in the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was not utilized for determining an appropriate tolerance level for the RACs of

asparagus, grass grown for seed, oats, okra, rhubarb, sorghum (grain and sweet), and sugarcane because the majority of treated samples bore residues below the LOQ.

Tolerances for the processed commodities of oats and sugarcane are not needed for the purpose of this petition based on the results of field trials which showed that residues of mesotrione were below the LOQ (<0.01 ppm) following treatment(s) at 3x and 5x. There are no processed commodities for grain sorghum that require tolerances at this time.

A tolerance summary for mesotrione is presented in Table 13. **A revised Section F should be submitted.**

There are no Codex, Canadian, or Mexican MRLs established for residues of mesotrione in crop or livestock commodities. Therefore, there are no issues of international harmonization raised by this action. An International Residue Limit Status (IRLS) sheet is appended to this document and follows this section.

Table 13. Tolerance Summary for Mesotrione.			
Commodity	Proposed Tolerance (ppm)	HED-Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
Asparagus	0.01	0.01	
Grass, seed screenings	0.10	0.10	
Grass, straw	0.10	0.10	
Grass, forage	0.01	0.01	
Grass, hay	0.01	0.01	
Oats, grain	0.01	0.01	*Oat,grain*
Oats, straw	0.01	0.01	*Oat, straw*
Oats, forage	0.01	0.01	*Oat, forage*
Oats, hay	0.01	0.01	*Oat, hay*
Okra	0.01	0.01	
Rhubarb	0.01	0.01	
Sorghum, forage	0.01	0.01	*Sorghum, grain, forage*
Sorghum, grain	0.01	0.01	*Sorghum, grain, grain*
Sorghum, stover	0.01	0.01	*Sorghum, grain, stover*
Sorghum, sweet	0.01	0.01	
Sugarcane	0.01	0.01	*Sugarcane, cane*

References

DP#: 260570
Subject: PP#8F04954. Mesotrione (Proposed Name). Multiresidue Method Testing of ZA1296. Chemical #: 122990. Case #: 289589. Submission #: S541377
From: S. Levy
To: F. Griffith
Date: 16-NOV-1999
MRID#: 44505224

DP#: 263245
Subject: Product Chemistry Review of Mesotrione (ZA 1296 Technical (dry)).
From: H. Podall
To: J. Tompkins/J. Stone
Date: 24-FEB-2000
MRID#s: 44373503-44373505, 44505003, 44505004, and 44901701

DP#: 274111
Subject: PP# 8F04954. Mesotrione: Health Effects Division (HED) Metabolism Assessment Review Committee (MARC) Meeting of 4/10/01. Chemical No. 122990. Case No. 063670. Submission No. S541375.
From: S. Levy
To: Y. Donovan
Date: 26-APR-2001
MRID#: None

DP#s: 245477 and 260267
Subject: PP#: 8F04954. Mesotrione in/on Field Corn. Evaluation of Residue Data and Analytical Methods. PC Code: 122990. Case #: 289589. Submission #s: S541377 and S569871.
From: S. Levy
To: J. Stone /J. Tompkins
Date: 06-JUN-2001
MRID#s: 44505118, 44505212-23, 44537109-12, 44901719, and 44942401-03

DP#: None
Subject: Reviewer's Guide and Summary of HED ChemSAC Approvals for Amending Commodity Definitions [40 CFR §180.1(h)] and Crop Group/Subgroups [40 CFR §180.41].
From: B. Schneider
To: H. Jamerson
Date: 14-JUN-2002
MRID#: None

DP#: 283827
Subject: Mesotrione. Summary of Analytical Chemistry and Residue Data for Sweet Corn, PP#2F06443, and Response to Data Deficiencies of a Previous HED Review (PP#8F04954, DP Barcodes: D245477 and D260267, 6/6/01, S. Levy).
From: W. Cutchin
To: J. Stone/J. Miller
Date: 12-JAN-2005
MRID#s: 45651801-45651803, 45651813, 45651814, 45651816, 45651817, and 45665901

DP#s: 326898 and 332812
Subject: Mesotrione. Section 3 Request for Use on Berry Group 13, Cranberry, Flax, and Millet (PP#6F7023) and Section 18 Request for Emergency Exemption Use on Grain Sorghum (Reg#: 06KS01). Summary of Analytical Chemistry and Residue Data.
From: S. Levy
To: J. Miller and A. Ertman
Dated: 3/2/07
MRIDs: 46726301-46726307

Attachments

Attachment 1: IRLS sheet
Attachment 2: Chemical Structures

cc: S.Levy
RDI: G.F. Kramer (05-DEC-2007), RAB1 Chemists (17-OCT-2007),
S. Levy: S-10953: PY1: (703)305-0783: 7509P: RAB1
Petition#: 6F7162
DP#: 338109
PC Code: 122990

Template Version September 2005

Attachment 1: IRLS sheet

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione	Common Name: Mesotrione	X Proposed tolerance ☐ Reevaluated tolerance ☐ Other	Date: 12-JUN-2007

Codex Status (Maximum Residue Limits)	U. S. Tolerances
X No Codex proposal step 6 or above ☐ Codex proposal step 6 or above for the crops requested	PP#: 6F7162 DP#: 338109 Other Identifier:
Residue definition (step 8/CXL): N/A	Reviewer/Branch: Sarah Levy, RAB1
	Residue definition: mesotrione (2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione; designated by the company code ZA1296)

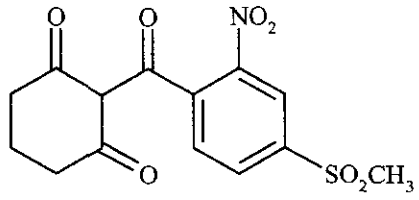
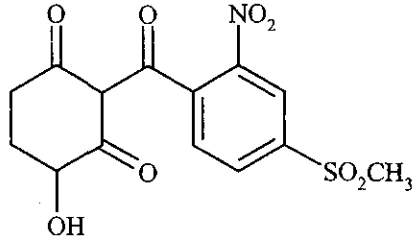
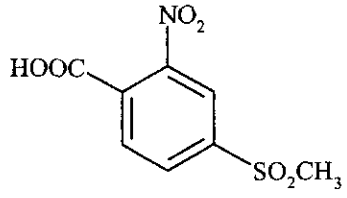
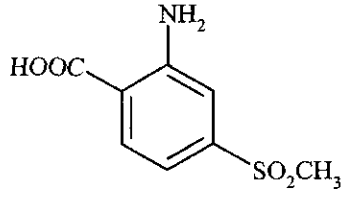
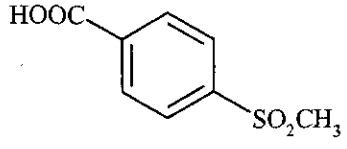
Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Asparagus	0.01
		Grass, seed screenings	0.10
		Grass, straw	0.10
		Grass, forage	0.01
		Grass, hay	0.01
		Oats, grain	0.01
		Oats, straw	0.01
		Oats, forage	0.01
		Oats, hay	0.01
		Okra	0.01
		Rhubarb	0.01
		Sorghum, forage	0.01
		Sorghum, stover	0.01
		Sorghum, grain	0.01
		Sorghum, sweet	0.01
		Sugarcane	0.01

Limits for Canada	Limits for Mexico
☐ No Limits X No Limits for the crops requested	X No Limits ☐ No Limits for the crops requested
Residue definition 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione	Residue definition: N/A

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)

Notes/Special Instructions: S. Funk, 14-JUN-2007.

Attachment 2: Chemical Names and Structures

Common name; Company code	*Chemical name*	Chemical structure
Mesotrione; ZA1296	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione	
4-OH-mesotrione; R282813	4-hydroxy-2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione	
MNBA	4-methanesulfonyl-2-nitro-benzoic acid	
AMBA	2-amino-4-methanesulfonyl-benzoic acid	
MBA	4-methanesulfonyl-benzoic acid	

Primary Evaluator: Sarah J. Levy, Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509P)

Date: 05-DEC-2007

Approved by: George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)

Date: 05-DEC-2007

This data-evaluation record (DER) was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 29-JUN-2007). The DER has been reviewed by the HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

MRID#: 47013808. Lin, K. (2006). Mesotrione - Magnitude of the Residue in or on Grain Sorghum. Project Number: T020419-04. Unpublished study prepared by Syngenta Crop Protection, Inc. 187 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection has submitted field trial data for mesotrione on grain sorghum. Twelve field trials were conducted in the U.S. during the 2005 growing season in Regions 2 (SC; 1 trial), 4 (LA; 1 trial), 5 (KS, MO, NE, and SD; 4 trials), 6 (OK and TX; 2 trials), 7 (NE; 1 trial), and 8 (CO, NM, and TX; 3 trials).

At each trial location, sorghum was treated with the 4 lb/gal flowable concentrate (FlC) formulation at 0.2 lb ai/A using a combination of one or more of the following three treatment regimes: (i) a single soil-surface (SS) spray application made at planting (Treatment Regime No. 2); (ii) a single preplant incorporated (PPI) spray applications made at planting (Treatment Regime No. 3); and/or (iii) a single post-emergence over-the-top (POT) spray with the addition of 0.25% (v:v) nonionic surfactant (NIS) at 12" plant height (Treatment Regime No. 4). Applications were made in ~14-21 gallons/Acre (GPA) of water using ground equipment, except for one trial (SC) where applications were made in ~4-5 GPA of water, to simulate an aerial application rate.

Sorghum forage samples were collected 30 days after the POT application; stover and grain samples were collected at maturity. Preharvest intervals (PHIs) were not applicable for trials treated by SS spray or PPI at planting. Stover and grain samples were collected at maturity. Additional samples of forage were collected at 0, 9, 16, and 30 days after POT, stover and grain samples were collected 7 days prior to maturity (7P), at maturity, and 7 days after maturity (7A) to generate residue decline data. At two trials, grain samples were processed to generate aspirated-grain fractions (AGFs).

Samples of sorghum forage, stover, grain, and AGFs were analyzed for residues of mesotrione using Method RAM 366/01 (liquid chromatography with tandem mass-spectrometry detectors

(LC-MS/MS)). This method was previously reviewed and forwarded to the U.S. Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual (PAM) Volume II as a confirmatory enforcement method for plant commodities (Memo, W. Cutchin, 12-JAN-2005; DP#: 283827). The method was adequate for data collection based on acceptable concurrent method recoveries. The validated limit of quantitation (LOQ) was 0.01 ppm for mesotrione in/on grain sorghum commodities.

The maximum storage duration of sorghum samples from harvest to analysis was 330 days (~11 months). The petitioner referenced available storage stability data which demonstrate that mesotrione is stable in corn matrices and soybean seed stored frozen for up to 40-42 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477). The available corn and soybean storage stability data will support the storage conditions and durations of samples from the subject sorghum field trials.

Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of grain sorghum forage, stover, and grain following either a single SS or PPI application of the 4 lb/gal FlC formulation made at planting at 0.2 lb ai/A (Treatment Regimes No. 2 and 3). Maximum residues of mesotrione were 0.02 ppm in/on samples of grain sorghum forage harvested 30 days following a single POT application of the 4 lb/gal FlC formulation at 0.2 lb ai/A (Treatment Regime No. 4). No residues of mesotrione were found in any of the sorghum stover, grain, or AGF samples harvested at maturity following Treatment Regime No. 4.

In the residue decline trials, detectable residues of mesotrione were found in 0-day sorghum forage samples and declined to below the LOQ (<0.01 ppm) by the 9-day PHI and remained below the LOQ at the 30-day PHI. Residues were below the LOQ (<0.01 ppm) in/on all samples of sorghum stover and grain collected at all sampling intervals.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial and processing residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP#: 338109].

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Mesotrione is a triketone herbicide which inhibits the enzyme *p*-hydroxyphenylpyruvate dioxygenase (HPPD), disrupting carotenoid biosynthesis. This process leads to the destruction of chlorophyll, resulting in a bleaching effect in susceptible plants. Mesotrione is intended for

preemergence and postemergence use for selective control of annual broadleaf weeds in field, pop, and sweet corn. The nomenclature of mesotrione is summarized in Table A.1, and the physicochemical properties of mesotrione are summarized in Table A.2.

TABLE A.1. Mesotrione Nomenclature.

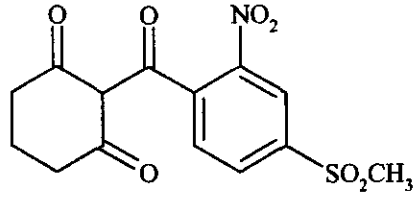
Chemical structure	
Common name	Mesotrione
Company experimental name	ZA1296
IUPAC name	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
CAS name	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
CAS registry number	104206-82-8
End-use product (EP)	4 lb/gal FlC (Callisto® Herbicide; EPA Reg. No. 100-1131)

TABLE A.2. Physicochemical Properties of Mesotrione.

Parameter	Value	Reference
Melting range	148.7-152.5°C	RD Memo, H. Podall, 24-FEB-2000; DP#: 263245.
pH	3.4 (1% dispersion in water; 25°C)	
Density	1.46 g/mL, 20°C	
Water solubility	20°C 160 ppm, unbuffered water 0.22 g/100 mL, pH 4.8 1.5 g/100mL, pH 6.9 2.2 g/100 mL, pH 9	
Solvent solubility	20°C 0.37 g/100 mL, methanol 1.7 g/100 mL, ethyl acetate 0.27 g/100 mL, toluene 10.4 g/100 mL, acetonitrile <0.03 g/100 mL, heptane 8.1 g/100 mL, acetone	
Vapor pressure	4.3 x 10^{-8} torr, 20°C	
Dissociation constant, pK_a	3.12, 20°C	
Octanol/water partition coefficient, Log(K_{OW})	20°C log P_{OW} = 0.11 in unbuffered water log P_{OW} = 0.90 in pH 5 buffer log P_{OW} <-1 at pH 7 and 9 buffered water	
UV/visible absorption spectrum	Absorption maximum in methanol at 256 mu, with a molar extinction coefficient of 2.24 x 104 M cm.	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Twelve field trials were conducted in the United States during the 2005 growing season in Regions 2 (SC; 1 trial), 4 (LA; 1 trial), 5 (KS, MO, NE, and SD; 4 trials), 6 (OK and TX; 2 trials), 7 (NE; 1 trial), and 8 (CO, NM, and TX; 3 trials).

Each trial site consisted of one untreated plot (Treatment Regime No. 1) and two to three treated plots (Treatment Regimes Nos. 2, 3, and 4). The study use pattern is presented in Table B.1.2. At each trial location, sorghum was treated with the 4 lb/gal FlC formulation at 0.2 lb ai/A using one of the following three treatment regimes: (i) a single SS spray application made at planting (Treatment Regime No. 2); (ii) a single PPI spray applications made at planting (Treatment Regime No. 3); or (iii) a single POT spray with the addition of 0.25% (v:v) NIS at 12" plant height (Treatment Regime No. 4). Applications were made in ~14-21 gal/A of water using ground equipment, except for one trial (SC) where applications were made in ~4-5 gal/A of water, to simulate an aerial application rate.

Sorghum forage samples were collected 30 days after the POT application; stover and grain samples were collected at maturity. PHIs were not applicable for trials treated by SS spray or PPI at planting. Stover and grain samples were collected at maturity. Additional samples of forage were collected at 0, 9, 16, and 30 days after POT, stover and grain samples were collected 7 days prior to maturity (7P), at maturity, and 7 days after maturity (7A) to generate residue decline data. At two trials, grain samples were processed to generate AGFs.

Sorghum was grown under normal agricultural conditions. The petitioner reported cultural practices and maintenance pesticides and fertilizers used at each site. Trial site conditions are presented in Table B.1.1. The crop varieties grown are identified in Table C.3. The petitioner included the overall monthly rainfall and temperature ranges for each trial site and stated that actual temperatures and rainfall amounts were within the average historical ranges at all trial sites. Irrigation was used to supplement rainfall as needed.

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State; Year (Trial No.)	Soil characteristics[1]			
	Type	%OM	pH	CEC (meq/g)
Elko, SC; 2005 (SJ-HR-05-6225)	Loamy Sand	1.3	6.2	4.2
Cheneyville, LA; 2005 (SD-HR-05-6226)	Loam	1.0	6.4	6.4
Highland, KS; 2005 (ND-HR-05-6227)	Silt Loam	2.6	6.8	13.0
York, NE; 2005 (NB-HR-05-6228)	Silty Clay Loam	2.8	6.4	19.1
LaPlata, MO; 2005 (ND-HR-05-6229)	Silty Clay Loam	4.4	7.1	21.9
Lesterville, SD; 2005 (NF-HR-05-6230)	Loam	2.5	6.7	21.8
Wharton, TX ; 2005 (SA-HR-05-6231)	Silt Loam	0.9	7.3	22.2
Hinton, OK; 2005 (SC-HR-05-6232)	Sandy Loam	0.72	6.0	7.0
Grand Island, NE; 2005 (NB-HR-05-6233)	Clay Loam	2.7	6.6	21.8
Levelland, TX; 2005 (SC-HR-05-6234)	Sandy Clay Loam	0.4	7.9	13.4
Ault, CO; 2005 (NM-HR-05-6235)	Sandy Clay Loam	1.6	8.3	30.4
Rincon, NM; 2005 (SC-HR-05-6236)	Loam	1.0	8.3	35.4

OM = organic matter; CEC = cation-exchange capacity.

TABLE B.1.2. Study Use Pattern.

Trial Identification: City, State; Year (Trial No.)	EP[1]	Application						Tank Mix/ Adjuvants
		Treat-ment No.[2]	Method; Timing[2]	Volume[3] (GPA)	Rate (lb ai/A)	RTI[4] (days)	Total Rate (lb ai/A)	
Elko, SC; 2005 (SJ-HR-05-6225)	4 lb/gal FlC	2	1. SS; at planting	4.6	0.2	NA	0.2	NA
		3	1. PPI; at planting	4.6	0.2	NA	0.2	NA
		4	1. POT; ~12" height	4.4	0.2	NA	0.2	NIS[5] 0.25% v:v
Cheneyville, LA; 2005 (SD-HR-05-6226)	4 lb/gal FlC	2	1. SS; at planting	15.5	0.2	NA	0.2	NA
		3	1. PPI; at planting	15.3	0.2	NA	0.2	NA
		4	1. POT; ~12" height	15.2	0.2	NA	0.2	NIS 0.25% v:v
Highland, KS; 2005 (ND-HR-05-6227)	4 lb/gal FlC	2	1. SS; at planting	14.6	0.2	NA	0.2	NA
		4	1. POT; ~12" height	13.8	0.2	NA	0.2	NIS 0.25% v:v
York, NE; 2005 (NB-HR-05-6228)	4 lb/gal FlC	3	1. PPI; at planting	20.0	0.2	NA	0.2	NA
		4	1. POT; ~12" height	19.9	0.2	NA	0.2	NIS 0.25% v:v
LaPlata, MO; 2005 (ND-HR-05-6229)	4 lb/gal FlC	2	1. SS; at planting	15.3	0.2	NA	0.2	NA
		4	1. POT; ~12" height	17.3	0.2	NA	0.2	NIS 0.25% v:v
Lesterville, SD; 2005 (NF-HR-05-6230)	4 lb/gal FlC	3	1. PPI; at planting	20.1	0.2	NA	0.2	NA
		4	1. POT; ~12" height	18.7	0.2	NA	0.2	NIS 0.25% v:v
Wharton, TX ; 2005 (SA-HR-05-6231)	4 lb/gal FlC	2	1. SS; at planting	21.0	0.2	NA	0.2	NA
		4	1. POT; ~12" height	19.5	0.2	NA	0.2	NIS 0.25% v:v

TABLE B.1.2. Study Use Pattern.

Trial Identification: City, State; Year (Trial No.)	EP[1]	Application						Tank Mix/ Adjuvants
		Treat-ment No.[2]	Method; Timing[2]	Volume[3] (GPA)	Rate (lb ai/A)	RTI[4] (days)	Total Rate (lb ai/A)	
Hinton, OK; 2005 (SC-HR-05-6232)	4 lb/gal FIC	3	1. PPI; at planting	13.9	0.2	NA	0.2	NA
		4	1. POT; ~12" height	13.2	0.2	NA	0.2	NIS 0.25% v:v
Grand Island; 2005 (NB-HR-05-6233)	4 lb/gal FIC	2	1. SS; at planting	19.9	0.2	NA	0.2	NA
		3	1. PPI; at planting	20.2	0.2	NA	0.2	NA
		4	1. POT; ~12" height	20.3	0.2	NA	0.2	NIS 0.25% v:v
Levelland, TX; 2005 (SC-HR-05-6234)	4 lb/gal FIC	3	1. PPI; at planting	15.1	0.2	NA	0.2	NA
		4	1. POT; ~12" height	15.4	0.2	NA	0.2	NIS 0.25% v:v
Ault, CO; 2005 (NM-HR-05-6235)	4 lb/gal FIC	2	1. SS; at planting	14.0	0.2	NA	0.2	NA
		4	1. POT; ~12" height	15.5	0.2	NA	0.2	NIS 0.25% v:v
Rincon, NM; 2005 (SC-HR-05-6236)	4 lb/gal FIC	2	1. SS; at planting	18.7	0.2	NA	0.2	NA
		3	1. PPI; at planting	18.5	0.2	NA	0.2	NA
		4	1. POT; ~12" height	17.3	0.2	NA	0.2	NIS 0.25% v:v

[1] EP = End-use Product; Callisto ® 4SC Herbicide (EPA Reg. No. 100-1131).
[2] Treatment Regime No. 2 = Single soil-surface (SS) spray made at planting; Treatment Regime No. 3 = Single preplant incorporated (PPI) made at planting; and Treatment Regime No. 4 = Single post-emergence over-the-top spray.
[3] GPA = Gallons per acre.
[4] RTI = Retreatment Interval; NA=not applicable because a single application was made.
[5] NIS = Nonionic surfactant.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Regions	Sorghum		
	Submitted	Requested	
		Canada	U.S.
2	1		1
4	1		1
5	4		4
6	2		2
7	1		1
8	3		3
Total	12		12

B.2. Sample Handling and Preparation

A single control and duplicate treated sorghum samples were collected from each trial site. Forage samples (~3 lbs) were collected 30 days after the POT application. Stover (~2 lbs) and grain (~3 lbs) samples were collected at maturity. Additional forage samples were collected at 0, 9, 16, and 30 days after POT, stover and grain samples were collected 7 days prior to maturity

(7P), at maturity, and 7 days after maturity (7A) to generate residue decline data. At two trials, bulk grain samples were processed to generate AGFs.

All samples were placed in frozen storage at the field sites, and were shipped frozen via ACDS truck to Syngenta Crop Protection (Greensboro, NC) for residue analysis. Samples were stored frozen (~-15 °C) at the analytical laboratory until preparation for extraction/analysis. Samples of forage and stover were prepared by cutting into 2" pieces with hand shears in the presence of dry ice. Grain samples were ground in a foodcutter in the presence of dry ice.

Bulk grain samples for processing were delivered frozen to GLP Technologies (Navasota, TX). Control and treated subsamples of sorghum grain (raw agricultural commodity (RAC)) were collected prior to processing. To generate the AGF samples, the grain sample was placed in a dust generation room and as the sample moved through the system, aspiration was used to remove light impurities. The light impurities were classified by sieving. After classification of each sample, all material through the 2360 micron sieve in both samples was recombined to form the AGF samples. After processing all samples were stored frozen prior to shipment to the analytical laboratory.

B.3. Analytical Methodology

Samples of sorghum commodities were analyzed for residues of mesotrione using LC-MS/MS method (RAM 366/01), entitled "Residue Analytical Method for the Determination of Residues of Mesotrione and 4-(Methylsufonyl)-2-Nitrobenzoic Acid (MNBA) in Crop Samples." A detailed description of the method was not included in the study. This method has been previously reviewed and was forwarded to FDA for inclusion in PAM Vol. II as a confirmatory enforcement method for plant commodities (Memo, W. Cutchin, 12-JAN-2005; DP#: 283827).

Briefly, homogenized samples were mixed with sodium chloride (10:1, wt:wt) and extracted with acetonitrile (ACN):water (1:1, v:v). An aliquot of the extract was diluted with water and the final volume adjusted with 90% water/methanol for LC-MS/MS analysis. The monitored ion transition was m/z 338 → 291. The validated LOQ was 0.01 ppm.

C. RESULTS AND DISCUSSION

Sample storage conditions and durations are summarized in Table C.2. Storage durations of sorghum samples from harvest to analysis were 176-330 days (5.8-10.9 months) for forage, 119-268 days (3.9-8.8 months) for stover and grain, and 229-235 days (7.5-7.7 months) for sorghum AGFs. The petitioner referenced available storage stability data which demonstrate that mesotrione is stable in corn matrices and soybean seed stored frozen for up to 40-42 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477). The available corn and soybean storage stability data will support the storage conditions and durations of samples from the subject sorghum field trials.

Samples of sorghum forage, stover, grain, and AGFs were analyzed for residues of mesotrione using LC-MS/MS method RAM 366/01. This method was previously reviewed and forwarded

to FDA for inclusion in PAM Vol. II as a confirmatory enforcement method for plant commodities (Memo, W. Cutchin, 12-JAN-2005; DP#: 283827). The method is adequate for data collection based on acceptable concurrent recovery data. The validated LOQ was 0.01 ppm. Recoveries were 71-119% for samples of untreated sorghum forage fortified with mesotrione at 0.01-20 ppm. Recoveries were 71-117% for samples of untreated sorghum stover and grain fortified with mesotrione at 0.01-2.0 ppm. Recoveries were 79-89% for samples of untreated sorghum AGFs fortified with mesotrione at 0.01-0.1 ppm. Adequate sample calculations and chromatograms were provided. Apparent residues of mesotrione were below the LOQ in/on twelve untreated samples each of sorghum forage, stover, and grain and in two untreated samples of AGFs.

Residue data from the sorghum field trials are reported in Table C.3. A summary of the residue data for sorghum forage, stover, grain, and AGFs is presented in Table C.4. Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of sorghum forage, stover, and grain following a single SS or PPI application of the 4 lb/gal FlC formulation at 0.2 lb ai/A (Treatment Regimes No. 2 and 3). Residues of mesotrione were below the LOQ (<0.01 ppm) to 0.02 ppm in/on samples of sorghum forage harvested 30 days following a single POT application of the 4 lb/gal FlC formulation at 0.2 lb ai/A (Treatment Regime No. 4). No residues of mesotrione were found in any of the sorghum stover, grain, or AGF samples harvested at maturity following Treatment Regime No. 4. A processing factor was not calculated for AGFs.

In the residue decline trials, residues of mesotrione were 11.8-15.1 ppm in/on sorghum forage samples collected at a 0-day PHI following a single POT application of the 4 lb/gal FlC formulation at 0.2 lb ai/A and declined to below the LOQ (<0.01 ppm) by the 9-day PHI and remained below the LOQ at the 30-day PHI. Residues were below the LOQ (<0.01 ppm) in/on all samples of sorghum stover and grain collected at all sampling intervals.

TABLE C.1. Summary of Concurrent Recoveries of Mesotrione from Grain Sorghum.

Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± SD[1] (%)
Forage	0.01	12	71, 72, 75, 79, 85, 87, 87, 91, 92, 93 94, 105	86 ± 10
	0.05	3	79, 85, 98	87 ± 10
	0.1	2	80, 102	91
	0.2	2	90, 97	94
	0.5	1	80	80
	1	1	94	94
	2	1	119	119
	20	2	92, 105	99
	Total	**24**	**71-119**	**90 ± 11**
Stover	0.01	13	71, 74, 75, 75, 76, 85, 85, 85, 88, 92, 92, 94, 94	84 ± 8
	0.02	1	75	75
	0.05	1	83	83
	0.1	1	112	112
	0.2	1	95	95
	0.5	1	91	91

TABLE C.1. Summary of Concurrent Recoveries of Mesotrione from Grain Sorghum.

Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± SD[1] (%)
	1	2	87, 97	92
	2	1	96	96
	Total	**21**	**71-112**	**87 ± 10**
Grain	0.01	12	73, 75, 82, 85, 88, 91, 91, 94, 95, 97, 99, 107	90 ± 10
	0.05	4	72, 79, 80, 82	78 ± 4
	0.1	3	91, 91, 93	92 ± 1
	0.2	3	93, 93, 117	101 ± 14
	0.5	3	90, 92, 112	98 ± 12
	1	1	94	94
	2	1	105	105
	Total	**27**	**72-117**	**91 ± 11**
AGF	0.01	2	79, 85	82
	0.1	2	86, 89	88
	Total	**4**	**79-89**	**85 ± 4**

[1] Standard deviation is applicable only for groups ≥ 3 samples.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability[2]
Sorghum forage	-15	176-330 days (~6-11 months)	Residues of mesotrione are relatively stable in/on fortified soybean seed and corn matrices (forage, stover and grain) stored frozen for 40-42 months.
Sorghum stover		119-268 days (~4-9 months)	
Sorghum grain		119-268 days (~4-9 months)	
AGF		235 days (~8 months)	

[1] Duration from harvest to analysis. All samples were analyzed within 7 days of extraction.
[2] Memo, S. Levy, 06-JUN-2001; DP# 245477.

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial ID (City, State; Year)	Region	Crop; Variety	Commodity or Matrix	Treatment Regime No.[1]	Total Rate (lb ai/A)	PHI[2] (days)	Mesotrione Residues (ppm)
Elko, SC; 2005 (SJ-HR-05-6225)	2	Sorghum; NK8416	Forage	2. SS	0.2	NA	<0.01, <0.01
				3. PPI	0.2	NA	<0.01, <0.01
				4. POT	0.2	30	<0.01, <0.01
			Stover	2. SS	0.2	Maturity	<0.01, <0.01
				3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
			Grain	2. SS	0.2	Maturity	<0.01, <0.01
				3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
Cheneyville, LA; 2005 (SD-HR-05-6226)	4	Sorghum; Pioneer 83G66	Forage	2. SS	0.2	NA	<0.01, <0.01
				3. PPI	0.2	NA	<0.01, <0.01
				4. POT	0.2	30	<0.01, <0.01
			Stover	2. SS	0.2	Maturity	<0.01, <0.01
				3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
			Grain	2. SS	0.2	Maturity	<0.01, <0.01
				3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
Highland, KS; 2005 (ND-HR-05-6227)	5	Sorghum; Dekalb DKS5400	Forage	2. SS	0.2	NA	<0.01, <0.01
				4. POT	0.2	30	<0.01, <0.01
			Stover	2. SS	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
			Grain	2. SS	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
			Grain (prior to processing)	4. POT	0.2	Maturity	<0.01, <0.01
			AGF[3]	4. POT	0.2	Maturity	<0.01, <0.01
York, NE; 2005 (NB-	5	Sorghum; NC+6B50	Forage	3. PPI	0.2	NA	<0.01, <0.01
					0.2	0	<0.01, <0.01

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial ID (City, State; Year)	Region	Crop; Variety	Commodity or Matrix	Treatment Regime No.[1]	Total Rate (lb ai/A)	PHI[2] (days)	Mesotrione Residues (ppm)
HR-05-6228)						9	<0.01, <0.01
						16	<0.01, <0.01
						30	<0.01, <0.01
				4. POT	0.2	0	14.4, 11.8
						9	<0.01, <0.01
						16	<0.01, <0.01
						30	<0.01, <0.01
			Stover	3. PPI	0.2	7P	<0.01, <0.01
						Maturity	<0.01, <0.01
						7A	<0.01, <0.01
				4. POT	0.2	7P	<0.01, <0.01
						Maturity	<0.01, <0.01
						7A	<0.01, <0.01
York, NE; 2005 (NB-HR-05-6228); *continued*	5	Sorghum; NC+6B50	Grain	3. PPI	0.2	7P	<0.01, <0.01
						Maturity	<0.01, <0.01
						7A	<0.01, <0.01
				4. POT	0.2	7P	<0.01, <0.01
						Maturity	<0.01, <0.01
						7A	<0.01, <0.01
LaPlata, MO; 2005 (ND-HR-05-6229)	5	Sorghum; Pioneer 8500	Forage	2. SS	0.2	NA	<0.01, <0.01
				4. POT	0.2	30	<0.01, <0.01
			Stover	2. SS	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
			Grain	2. SS	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
Lesterville, SD; 2005 (SJ-HR-05-6230)	5	Sorghum; Partner 251	Forage	3. PPI	0.2	NA	<0.01, <0.01
				4. POT	0.2	30	<0.01, <0.01
			Stover	3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
			Grain	3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
Wharton, TX ; 2005 (SA-HR-05-6231)	6	Sorghum; DK52	Forage	2. SS	0.2	NA	<0.01, <0.01
						0	<0.01, <0.01
						9	<0.01, <0.01
						16	<0.01, <0.01
						30	<0.01, <0.01

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial ID (City, State; Year)	Region	Crop; Variety	Commodity or Matrix	Treatment Regime No.[1]	Total Rate (lb ai/A)	PHI[2] (days)	Mesotrione Residues (ppm)
Wharton, TX ; 2005 (SA-HR-05-6231); *continued*	6	Sorghum; DK52	Forage	4. POT	0.2	0	15.0, 15.1
						9	<0.01, <0.01
						16	<0.01, <0.01
						30	<0.01, <0.01
			Stover	2. SS	0.2	7P	<0.01, <0.01
						Maturity	<0.01, <0.01
						7A	<0.01, <0.01
				4. POT	0.2	7P	<0.01, <0.01
						Maturity	<0.01, <0.01
						7A	<0.01, <0.01
			Grain	2. SS	0.2	7P	<0.01, <0.01
						Maturity	<0.01, <0.01
						7A	<0.01, <0.01
				4. POT	0.2	7P	<0.01, <0.01
						Maturity	<0.01, <0.01
						7A	<0.01, <0.01
Hinton, OK; 2005 (SC-HR-05-6232)	6	Sorghum; SG95207	Forage	3. PPI	0.2	NA	<0.01, <0.01
				4. POT	0.2	30	<0.01, <0.01
			Stover	3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
			Grain	3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
Grand Island, NE; 2005 (NB-HR-05-6233)	7	Sorghum; NC+6B50	Forage	2. SS	0.2	NA	<0.01, <0.01
				3. PPI	0.2	NA	<0.01, <0.01
				4. POT	0.2	30	<0.01, <0.01
			Stover	2. SS	0.2	Maturity	<0.01, <0.01
				3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
			Grain	2. SS	0.2	Maturity	<0.01, <0.01
				3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
Levelland, TX; 2005 (SC-HR-05-6234)	8	Sorghum; F222E	Forage	3. PPI	0.2	NA	<0.01, <0.01
				4. POT		30	<0.01, <0.01
			Stover	3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT		Maturity	<0.01, <0.01
			Grain	3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT		Maturity	<0.01, <0.01
			Grain (prior to processing)	4. POT	0.2	Maturity	<0.01, <0.01
			AGF[3]	4. POT	0.2	Maturity	<0.01, <0.01
Ault, CO; 2005 (MN-	8	Sorghum; DG-720B	Forage	2. SS	0.2	NA	<0.01, <0.01
				4. POT	0.2	30	<0.01, <0.01

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial ID (City, State; Year)	Region	Crop; Variety	Commodity or Matrix	Treatment Regime No.[1]	Total Rate (lb ai/A)	PHI[2] (days)	Mesotrione Residues (ppm)
HR-05-6235)			Stover	2. SS	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
			Grain	2. SS	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
Rincon, NM; 2005 (SC-HR-05-6236)	8	Sorghum; 7117	Forage	2. SS	0.2	NA	<0.01, <0.01
				3. PPI	0.2	NA	<0.01, <0.01
				4. POT	0.2	30	0.02, 0.01
			Stover	2. SS	0.2	Maturity	<0.01, <0.01
				3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01
			Grain	2. SS	0.2	Maturity	<0.01, <0.01
				3. PPI	0.2	Maturity	<0.01, <0.01
				4. POT	0.2	Maturity	<0.01, <0.01

[1] Treatment Regime No. 2 = Single (SS spray made at planting; Treatment Regime No. 3 = Single PPI made at planting; and Treatment Regime No. 4 = Single POT spray.

[2] PHIs were NA for trials treated by SS spray or PPI at planting. Stover and grain samples were collected at maturity. In the decline trials, forage was collected at 0, 9, 16, and 30 days after POT application, and stover and grain were collected 7 days prior to maturity (7P) and 7 days after maturity (7A).

[3] AGF = aspirated-grain fraction.

TABLE C.4. Summary of Residue Data from Crop Field Trials with Mesotrione.

Commodity	Total Applic. Rate (lb ai/A)	PHI[1] (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT[2]	Median	Mean	SD
Treatment Regime No. 2: Single SS spray made at planting									
Sorghum, forage	0.2	NA	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Sorghum, stover	0.2	Maturity	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Sorghum, grain	0.2	Maturity	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Treatment Regime No. 3: Single PPI made at planting									
Sorghum, forage	0.2	NA	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Sorghum, stover	0.2	Maturity	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Sorghum, grain	0.2	Maturity	16	<0.01	<0.01	<0.01	<0.01	<0.01	--
Treatment Regime No. 4: Single POT									
Sorghum, forage	0.2	30	24	<0.01	0.02	0.02	<0.01	<0.01	0.002
Sorghum, stover	0.2	Maturity	24	<0.01	<0.01	<0.01	<0.01	<0.01	--
Sorghum, grain	0.2	Maturity	24	<0.01	<0.01	<0.01	<0.01	<0.01	--
AGF	0.2	Maturity	2	<0.01	<0.01	<0.01	<0.01	<0.01	--

[1] PHIs were not applicable (NA) for trials treated by SS spray or PPI at planting. Stover and grain samples were collected at maturity.
[2] HAFT = Highest-Average Field Trial.

D. CONCLUSION

The submitted field trial data are acceptable and reflect a single application of the 4 lb/gal FlC formulation at 0.2 lb ai/A either by a SS spray at planting, a PPI spray made at planting, or a single POT spray with the addition of 0.25% (v:v) (NIS) at 12" plant height. An acceptable method was used for quantitation of residues in/on sorghum commodities, and adequate data are available to support sample storage durations and conditions.

Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of sorghum forage, stover, and grain following either a single SS or PPI application of the 4 lb/gal FlC formulation made at planting at 0.2 lb ai/A (Treatment Regimes No. 2 and 3). Maximum residues of mesotrione were 0.02 ppm in/on samples of sorghum forage harvested 30 days following a single POT application of the 4 lb/gal FlC formulation at 0.2 lb ai/A (Treatment Regime No. 4). No residues of mesotrione were found in any of the sorghum stover, grain, or AGF samples harvested at maturity following Treatment Regime No. 4. A processing factor was not calculated for AGFs.

In the residue decline trials, detectable residues of mesotrione were found in 0-day sorghum forage samples and declined to below the LOQ (<0.01 ppm) by the 9-day PHI and remained

below the LOQ at the 30-day PHI. Residues were below the LOQ (<0.01 ppm) in/on all samples of sorghum stover and grain collected at all sampling intervals.

E. REFERENCES

DP#s: 245477 and 260267
Subject: PP#: 8F04954. Mesotrione in/on Field Corn. Evaluation of Residue Data and Analytical Methods. PC Code: 122990. DP Barcodes: D245477, and D260267. Case #: 289589. Submission #s: S541377, and S569871. MRID #s: 44505118, 44505212-23, 44537109-12, 44901719, and 44942401-03.
From: Sarah Levy
To: J.Stone/J.Tompkins
Date: 06-JUN-2001
MRID#: 47136802

DP#: 283827
Subject: Mesotrione. Summary of Analytical Chemistry and Residue Data for Sweet Corn, PP#2F06443, and Response to Data Deficiencies of a Previous HED Review (PP#8F04954, DP Barcodes: D245477 and D260267, 6/6/01, S. Levy).
From: William Cutchin
To: J. Stone/J. Miller
Date: 12-JAN-2005
MRID#: 45651803

DP#: 263245
Subject: Product Chemistry Review of Mesotrione (ZA 1296 Technical (dry)).
From: H. Podall
To: J. Tompkins/J. Stone
Date: 24-FEB-2000
MRID#s: 44373503-44373505, 44505003, 44505004, and 44901701

F. DOCUMENT TRACKING

RDI: G.F. Kramer (05-DEC-2007), RAB1 Chemists (03-OCT-2007)
S. Levy:S10953:PY1:(703)305-0783:7509P:RAB1
Petition #: 6F7162
DP#: 338109
PC Code: 122990

Template Version June 2005

Mesotrione/ZA01296/PC Code 122990/Syngenta Crop Protection, Inc.
DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
Storage Stability – Blueberry, Asparagus, Sugarcane, and Okra

Primary Evaluator: Sarah J. Levy, Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509P)
Date: 05-DEC-2007

Approved by: George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)
Date: 05-DEC-2007

Note: This data-evaluation record (DER) was originally prepared by Tetrahedron, Inc, subcontractor for Versar, Inc. (6850 Versar Center, Springfield, VA 22151; submitted 31-MAY-2007). The DER has been reviewed by the HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORTS:

MRID#: 47013801. Lin, K., (2006). Mesotrione: Stability of Mesotrione Residues in Blueberry, Asparagus, Sugarcane and Okra Under Freezer Storage Conditions, Interim Report. Syngenta Report and Task Number: T004813-05. Unpublished study prepared by Syngenta Crop Protection, Inc. 43 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted the results of a storage stability study with mesotrione in blueberry, asparagus, sugarcane, and okra. Untreated samples of each of these commodities were composited, ground and fortified with mesotrione at a nominal fortification level of 1.0 ppm. Samples were placed in frozen storage at approximately -20°C and analyzed at storage intervals of 0, 1, 3, 6 and 13 months.

Samples of blueberry, asparagus, sugarcane, and okra commodities were analyzed for residues of mesotrione using the modified analytical method RAM 366/01 (liquid chromatography with tandem mass-spectrometry detectors (LC-MS/MS)). The limit of quantitation (LOQ) was 0.01 ppm. The method used in this study was a previously submitted confirmatory method (MRID 45651816, Memo, W. Cutchin, 12-JAN-2005; DP#: 283827), and upon review, it was stated that the analytical method "is adequate for use as a confirmatory method for enforcement purposes. The method will be forwarded to FDA (U.S. Food and Drug Administration) for inclusion in PAM (Pesticide Analytical Method) Volume II as a confirmatory method. Validation by EPA/ACB (Analytical Chemistry Branch) is not required for this method."

The storage stability data indicate that residues of mesotrione are stable at approximately -20°C for at least 13 months in blueberry, asparagus, sugarcane, and okra commodities.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the storage stability data are classified as scientifically acceptable.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP#: 338109].

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Mesotrione is a triketone herbicide which inhibits the enzyme *p*-hydroxyphenylpyruvate dioxygenase (HPPD), disrupting carotenoid biosynthesis. This process leads to the destruction of chlorophyll, resulting in a bleaching effect in susceptible plants. Mesotrione is intended for preemergence and postemergence use for selective control of annual broadleaf weeds in field, pop, and sweet corn. The nomenclature of mesotrione is summarized in Table A.1, and the physicochemical properties of mesotrione are summarized in Table A.2.

TABLE A.1. Test Compound Nomenclature.

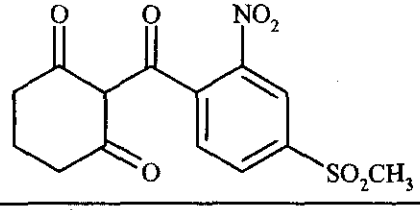
Compound	Chemical Structure
	
Common name	Mesotrione
Company experimental name	ZA01296
IUPAC name	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
CAS name	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
CAS #	104206-82-8
End-use product/(EP)	4 lb/gal SC (Callisto® Herbicide; EPA Reg. No. 100-1131)

TABLE A.2. Physicochemical Properties of the Parent Compound Mesotrione.		
Parameter	Value	Reference
Melting range	148.7 to 152.5°C	RD Memo, H. Podall, 24-FEB-2000; DP#: 263245.
pH	3.4 (1% dispersion in water; 25°C)	
Density	1.46 g/mL, 20°C	
Water solubility (20°C)	160 ppm, unbuffered water 0.22 g/100 mL, pH 4.8 1.5 g/100 mL, pH 6.9 2.2 g/100 mL, pH 9	
Solvent solubility (20°C)	0.37 g/100 mL, methanol 1.7 g/100 mL, ethyl acetate 0.27 g/100 mL, toluene 10.4 g/100 mL, acetonitrile <0.03 g/100 mL, heptane 8.1 g/100 mL, acetone	
Vapor pressure (20°C)	4.3×10^{-8} torr	
Dissociation constant (pK_a) at 20°C	3.12	
Octanol/water partition coefficient Log(K_{OW}) at 20 °C	log Pow = 0.11 in unbuffered water log Pow = 0.90 in pH 5 buffer log Pow <-1 at pH 7 and 9 buffered water	
UV/visible absorption spectrum	Absorption maximum in methanol at 256 mu, with a molar extinction coefficient of 2.24×10^4 M cm	

B. EXPERIMENTAL DESIGN

B.1. Sample Handling and Preparation

Fortification standard solutions were freshly prepared as outlined in Analytical Method RAM 366/01. The standards were used for the preparation of calibration standards and fortifying the storage stability study samples.

Untreated blueberry, asparagus, sugarcane and okra samples were received from Syngenta's Dietary Safety Department Sample Inventory. Each crop type was composited and ground in a foodcutter. Dry ice was used as necessary to keep the samples frozen. After preparation, the composited samples were stored in labeled polyethylene bags or bottles and kept frozen until fortified. A total of 35 samples were weighed for each crop type. Each sample was prepared by weighing out 10 grams into a wide mouth jar. Storage stability samples were fortified at 1.0 ppm.

With the exception of the Day-0 samples, the fortified samples were immediately placed in frozen storage at approximately -20°C. The temperature was maintained and monitored constantly. Samples from Day-0 were analyzed immediately after fortification. One set was analyzed with a control and two freshly fortified controls at the following storage intervals: 1-month, 3-month, 6-months and 13-months. Therefore, a total of ten freshly fortified samples and a total of eight aged/stored fortified samples were analyzed for mesotrione in blueberry, asparagus, sugarcane and okra during the thirteen months of the study.

B.2. Analytical Methodology

Analyses of mesotrione in blueberry, asparagus, sugarcane and okra were performed according to Syngenta Analytical Method RAM 366/01 titled "Residue Analytical Method for the Determination of Residues of Mesotrione and 4-(methylsulfonyl)-2-Nitrobenzoic Acid (MNBA) in Crop Samples." The method was modified for analysis of residues of mesotrione in blueberry, asparagus, sugarcane and okra as follows: a 10-gram subsample was Polytron-homogenized for 3-5 minutes with 100 mL of 50% acetonitrile (CAN)/H_2O after addition of one gram of sodium chloride (NaCl). Approximately 40 mL of the mixture was centrifuged and an aliquot was taken from the supernatant and diluted with water. The final volume was adjusted with 90% H_2O/methanol (MeOH). The sample final solution was injected onto a LC-MS/MS method system for residue analysis. The LOQ was 0.01 ppm for mesotrione in all four crop types.

C. RESULTS AND DISCUSSION

Concurrent method recovery data are presented in Table C.1. The data indicate that modified Method RAM 366/01 is adequate for the determination of residues of mesotrione in/on blueberry, asparagus, sugarcane, and okra. Concurrent recoveries of mesotrione ranged from 81.0% to 107% for blueberry, from 86.0% to 110% for asparagus, from 80.0% to 96.0% for sugarcane and from 94.0% to 108% for okra.

The results of the storage stability studies are presented in Table C.2. The mean recovered residues of mesotrione from stored specimens ranged from 0.820 ppm to 0.995 ppm for blueberry, from 0.920 ppm to 0.985 ppm for asparagus, from 0.755 ppm to 0.880 ppm for sugarcane and from 0.890 ppm to 1.02 ppm for okra. Correction factors were applied to the residues found in stored specimens based on the average concurrent recoveries less than 100%. Correction factors were not applied for concurrent recoveries equal to or greater than 100%. The corrected recoveries ranged from 91% to 105% for blueberry, from 94.5% to 111% for asparagus, from 89% to 109% for sugarcane and from 89% to 106% for okra.

Based on the reported data, residues of mesotrione are stable in/on blueberry, asparagus, sugarcane and okra stored frozen at approximately -20°C for up to 13 months. There were no residues of mesotrione detected in any of the non-fortified controls analyzed.

A graph of the storage stability of residues of mesotrione is presented in Figure C.1.

TABLE C.1. Summary of Concurrent Recoveries of Residues of Mesotrione in Various Commodities.

Matrix	Spike Level (ppm)	Storage Interval (months)	Sample Size (n)	Recoveries (%)	Mean* (%)
Blueberry	1.0	0	2	90, 86	88.0
		1	2	81, 95	88.0
		3	2	94, 96	95.0
		6	2	93, 96	94.5
		13	2	100, 107	104
Asparagus	1.0	0	2	91, 86	88.5
		1	2	101, 110	106
		3	2	96, 99	97.5
		6	2	99, 94	96.5
		13	2	95, 96	95.5
Sugarcane	1.0	0	2	86, 83	84.5
		1	2	80, 81	80.5
		3	2	91, 92	91.5
		6	2	92, 96	94.0
		13	2	83, 91	87.0
Okra	1.0	0	2	94, 97	95.5
		1	2	104, 102	103
		3	2	108, 98.0	103
		6	2	100, 98.0	99.0
		13	2	96, 95	95.5

*Standard deviations for mean values were not calculated because the number of individual values used to calculate the mean was less than three.

FIGURE C.1. Graph of the Stability of Fortified Residues of Mesotrione in Various Commodities.

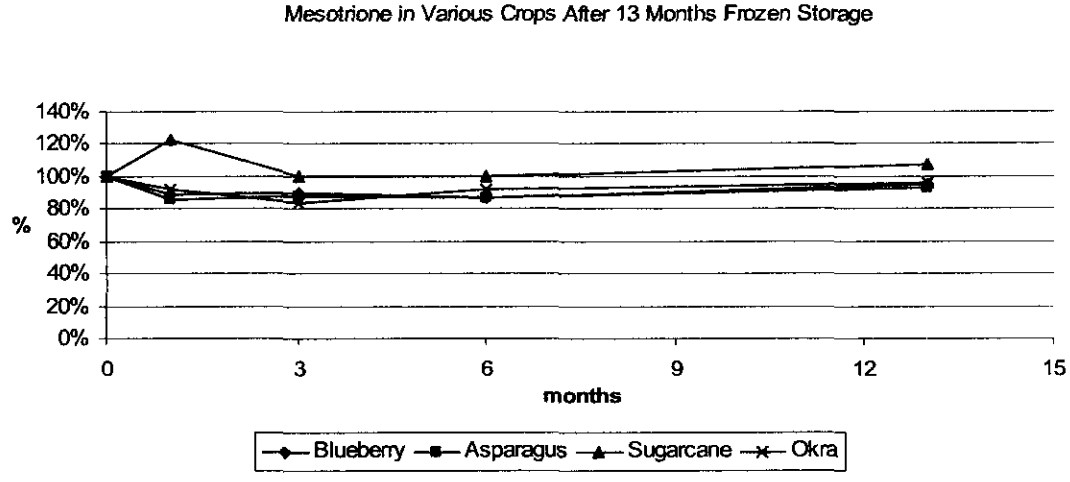


TABLE C.2. Stability of Residues of Mesotrione in Various Commodities Following Storage at ≤-20 °C.

Commodity	Spike Level (ppm)	Storage Interval (months)	Recovered Residues (ppm)	Mean Recovered Residues (ppm)	Mean Recovery (%)	Corrected % Recovery[1]
Blueberry	1.0	0	0.92, 0.93	0.925	92.5	105
		1	0.83, 0.81	0.820	82.0	93
		3	0.90, 0.89	0.895	89.5	94
		6	0.82, 0.90	0.860	86.0	91
		13	0.98, 1.01	0.995	99.5	99.5[2]
Asparagus	1.0	0	0.92, 1.04	0.980	98.0	111
		1	0.97, 0.92	0.945	94.5	94.5[2]
		3	0.92, 0.96	0.940	94.0	96
		6	0.94, 0.90	0.920	92.0	95
		13	0.98, 0.99	0.985	98.5	103
Sugarcane	1.0	0	0.77, 0.74	0.755	75.5	89
		1	0.89, 0.87	0.880	88.0	109
		3	0.81, 0.83	0.820	82.0	90
		6	0.83, 0.84	0.835	83.5	89
		13	0.80, 0.86	0.830	83.0	95
Okra	1.0	0	1.02, 1.01	1.015	101.5	106
		1	0.98, 0.96	0.970	97.0	97[2]
		3	0.87, 0.91	0.890	89.0	89[2]
		6	0.94, 0.99	0.965	96.5	97
		13	0.98, 0.97	0.975	97.5	102

[1] Corrected for mean concurrent recovery (see TABLE C.1).
[2] Average % recovery for the fresh fortification was >100%, therefore aged fortification was not adjusted.

D. CONCLUSION

The submitted storage stability results adequately demonstrate the stability of residues of mesotrione in/on blueberry, asparagus, sugarcane, and okra stored frozen for at least 13 months. An acceptable method was used for the quantitation of residues in the tested commodities.

E. REFERENCES

DP#: 263245
Subject: Product Chemistry Review of Mesotrione (ZA 1296 Technical (dry)).
From: H. Podall
To: J. Tompkins/J. Stone
Date: 24-FEB-2000
MRID#s: 44373503-44373505, 44505003, 44505004, and 44901701

DP#:	283827
Subject:	Mesotrione. Summary of Analytical Chemistry and Residue Data for Sweet Corn, PP#2F06443, and Response to Data Deficiencies of a Previous HED Review (PP#8F04954, DP Barcodes: D245477 and D260267, 6/6/01, S. Levy).
From:	William Cutchin
To:	J. Stone/J. Miller
Date:	12-JAN-2005
MRID#:	45651803

F. DOCUMENT TRACKING

RDI: G.F. Kramer (05-DEC-2007), RAB1 Chemists (26-SEP-2007)
S. Levy:S10953:PY1:(703)305-0783:7509P:RAB1
Petition #: 6F7162
DP#: 338109
PC Code: 122990

Template Version June 2005

Mesotrione/ZA01296/Syngenta Crop Protection, Inc.
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial/ Residue Decline – Asparagus

Primary Evaluator: Sarah J. Levy, Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509P)
Date: 05-DEC-2007

Approved by: George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)
Date: 05-DEC-2007

Note: This data-evaluation record (DER) was originally prepared by Tetrahedron, Inc, subcontractor for Versar, Inc. (6850 Versar Center, Springfield, VA 22151; submitted 31-MAY-2007). The DER has been reviewed by the HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORTS:

MRID#: 47013802. Lin, K. (2006). Mesotrione - Magnitude of the Residues in or on Asparagus. Lab Project Number: T021572-04. Unpublished study prepared by Syngenta Crop Protection, Inc. 90 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted field trial data for mesotrione in/on asparagus. Eight field trials (seven harvest and one decline) were conducted in the U.S. encompassing Regions 2 (1 trial in North Carolina), 5 (2 trials in Michigan), 10 (3 trials in California), 11 (1 trial in Oregon), and 11 (1 trial in Washington) during the 2005 growing season. At each trial location, there was one untreated and 3 treated plots.

The treated plots were treated with Callisto® 4SC (a 4 lbs ai/gal soluble-concentrate formulation), using one of the following three regimes: (1) by one time pre-emergence soil-surface (PSS) spray at a rate of 0.24 lbs ai/A (269 g ai/ha); (2) by a PSS spray at a rate of 0.24 lbs ai/A followed by a post-emergence over-the-top (POT) spray at 0.094 lbs ai/A (105 g ai/ha); and (3) by one time POT spray at 0.094 lbs ai/A. Total treatment regime volume ranged from 2-41 gallons/acre (GPA). An adjuvant was added to the spray mixture for the second and third application regimes.

For each of the field trials, one untreated and two treated mature asparagus raw agricultural commodity (RAC) samples were collected after each of the spraying regimes. Pre-harvest intervals (PHIs) were not applicable for the PSS spray (regime 1). Samples were collected two days following the regime 2 and 3 test substance application [2-day PHI]. Samples from one CA trial site (WD-HR-05-6274) were collected at 3 days PHI interval. In addition, at one MI trial site (Trial NL-HR-05-6271), asparagus samples were harvested at 0, 1, 2, and 3 days after the last application to determine residue decline.

Asparagus samples were analyzed for residues of mesotrione using method RAM 366/01 (liquid chromatography with tandem mass-spectrometry detectors (LC-MS/MS)), with modifications. This method was previously reviewed and forwarded to the U.S. Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual (PAM) Volume II as a confirmatory

enforcement method for plant commodities (Memo, W. Cutchin, 12-JAN-2005; DP#: 283827). The method was adequate for data collection based on acceptable concurrent method recoveries. The validated limit of quantitation (LOQ) was 0.01 ppm for mesotrione in/on asparagus.

Asparagus samples were stored frozen prior to analysis; the maximum storage interval from harvest to extraction was 18 months. Sample storage intervals between sampling, extraction and analysis ranged from 13 to 18 months. Mesotrione residues were found to be stable in asparagus under freezer storage conditions for at least 13 months (refer to 47013801.der). In addition, residues of mesotrione were found to be stable in corn grain, corn forage, corn fodder, soybean seed, and radish root for up to 40 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477). Based on these results, residues of mesotrione are expected to be stable in asparagus over the storage interval of this study.

Residues of mesotrione treated by PSS spray only at a total rate of 0.24 lbs ai/A were less than the LOQ (0.01 ppm) in all samples. A PHI was not applicable.

The maximum residue of mesotrione was 0.25 ppm in/on asparagus harvested 2 days after PSS spray application followed by a POT spray (at a total rate of 0.334 lbs ai/A). The maximum residue of mesotrione was 0.67 ppm in/on asparagus harvested 2 days after POT spray only (at a total rate of 0.094 lbs ai/A). Residue decline data show that mesotrione residues generally decrease with increasing PHIs. Analysis of untreated control samples demonstrated that they were less then the LOQ (0.01 ppm).

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP#: 338109].

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The following deviations from regulatory requirements were reported: (1) Weather data were not collected according to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)-GLP requirements; National Oceanic and Atmospheric Administration (NOAA) weather data are to be reported; (2) Tank mix storage stability data were not generated as required in 40 CFR 160.113(a)(3); (3) Maintenance chemicals and irrigation were not applied under GLP; and (4) Soil characterization analysis was not conducted under GLP. These deviations did not impact the validity of the study.

A. BACKGROUND INFORMATION

Mesotrione is a triketone herbicide which inhibits the enzyme *p*-hydroxyphenylpyruvate dioxygenase (HPPD), disrupting carotenoid biosynthesis. This process leads to the destruction

of chlorophyll, resulting in a bleaching effect in susceptible plants. Mesotrione is intended for preemergence and postemergence use for selective control of annual broadleaf weeds in field, pop, and sweet corn. The nomenclature of mesotrione is summarized in Table A.1, and the physicochemical properties of mesotrione are summarized in Table A.2.

TABLE A.1. Mesotrione Nomenclature.

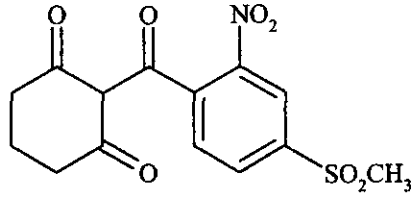
Chemical structure	
Common name	Mesotrione
Company experimental name	ZA01296
IUPAC name	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
CAS name	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
CAS registry number	104206-82-8
End-use product (EP)	4 lb/gal SC (Callisto® Herbicide; EPA Reg. No. 100-1131)

TABLE A.2. Physicochemical Properties of Mesotrione.

Parameter	Value	Reference
Melting range	148.7-152.5°C	RD Memo, H. Podall, 24-FEB-2000; DP#: 263245.
pH	3.4 (1% dispersion in water; 25°C)	
Density	1.46 g/mL, 20°C	
Water solubility	20°C 160 ppm, unbuffered water 0.22 g/100 mL, pH 4.8 1.5 g/100mL, pH 6.9 2.2 g/100 mL, pH 9	
Solvent solubility	20°C 0.37 g/100 mL, methanol 1.7 g/100 mL, ethyl acetate 0.27 g/100 mL, toluene 10.4 g/100 mL, acetonitrile <0.03 g/100 mL, heptane 8.1 g/100 mL, acetone	
Vapor pressure	4.3×10^{-8} torr, 20°C	
Dissociation constant, pK_a	3.12, 20°C	
Octanol/water partition coefficient, $Log(K_{OW})$	20°C log P_{OW} = 0.11 in unbuffered water log P_{OW} = 0.90 in pH 5 buffer log P_{OW} <-1 at pH 7 and 9 buffered water	
UV/visible absorption spectrum	*Absorption maximum in methanol at 256* mu, with a molar extinction coefficient of 2.24×10^4 M cm.	

B. EXPERIMENTAL DESIGN

Asparagus was grown under normal agricultural conditions in trial plots at each of the field trials. The control plots were separated sufficiently to exclude any contamination from the treated plots.

The asparagus plants at all eight trial sites were treated with Callisto® 4SC, a formulation of mesotrione, in three regimes: (1) by one time PSS spray at a rate of 0.24 lbs ai/A (269 g ai/ha); (2) by a PSS spray at a rate of 0.24 lbs ai/A followed by a POT spray at 0.094 lbs ai/A (105 g ai/ha); and (3) by one time POT spray at 0.094 lbs ai/A. The total nominal seasonal rate was 0.668 lb ai/A. Applications were made using ground equipment and backpack sprayers at a total treatment regime volume of 2 to 41 GPA. An adjuvant (non-ionic surfactant) was added to the tank mixes for the second and third application regimes.

Single untreated and duplicate treated samples of mature asparagus were harvested by hand 2 days after the post over-the-top application (2-day PHI). Samples from one CA trial site (WD-HR-05-6274) were collected at 3 days PHI. In addition, at one of the MI sites, one control and duplicate treated samples were also harvested at 0, 1, 2 and 3 days after the last application to determine residue decline. Samples were collected from the control plot first and then from the treated plot, avoiding the plot boundaries and row ends.

At least 2.5 pounds of RAC samples were collected from 24 separate asparagus plants. Duplicate samples were taken from each treated plot. Samples from decline trials were approximately at least 50% less then the above mentioned weight. After collection of the prerequisite number of spears, it was found that some samples had lower than expected weights at three sites: SJ-HR-05-6270, WD-HR-05-6274 and WC-HR-05-6275.

After collection, asparagus spear samples were stored frozen, and shipped frozen to Syngenta's Greensboro, NC facility via Agricultural Chemicals Development Service (ACDS).

Cultivation and trial maintenance methods were conducted in accordance with local agricultural practices; maintenance chemicals used at each trial site during the study were reported. Average monthly minimum and maximum temperatures, and total monthly precipitation amounts were reported for each trial from planting to harvest. According to the Study Report, temperature and precipitation were generally typical at each site as compared to historical 10-year data. The historical data were only reported for precipitation. No unusual weather conditions occurred during the study except for less than normal rainfall at three sites: SJ-HR-05-6270, NL-HR-05-6271 and NL-HR-05-6272. Supplementary irrigation was only provided at site WF-HR-05-6278 via overhead sprinkler.

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State, EPA Region; Year (Trial No.)	Soil characteristics[1]				Meteorological Data	
	Type	%OM	pH	CEC (meq/g)	Overall Monthly Rainfall Range (inches)	Overall Monthly Temperature Range (°F)
Clinton, NC, Region 2; 2005 (SJ-HR-05-6270)	Sandy Loam	1.9	6.3	6.1	2.8-2.9	23-85
Conklin, MI, Region 5; 2005 (NL-HR-05-6271)	Sand	2.3	5.7	5.6	0.4-2.2	1-79
Comstock, MI, Region 5; 2005 (NL-HR-05-6272)	Sandy Loam	1.6	7.2	6.3	0.8-2.0	26-83
Gonzales, CA, Region 10; 2005 (WC-HR-05-6273)	Loam	1.6	7.8	24	3.4-4.3	39-87
Walnut Grove, CA, Region 10; 2005 (WD-HR-05-6274)	Sandy Clay Loam	16.2	6.6	38.1	2.1-3.0	38-83
Fire Bough, CA, Region 10; 2005 (WC-HR-05-6275)	Clay Loam	2.7	7.7	25.9	0.3-3.7	25-69
Hermiston, OR, Region 11; 2005 (WF-HR-05-6277)	Silty Clay Loam	4.4	5.7	16.5	0.8-1.1	28-95
Ephrata, WA, Region 11; 2005 (WF-HR-05-6278)	Sandy Loam	0.9	7.2	12.7	0.5-1.8	29-92

[1] OM = organic matter; CEC = cation-exchange capacity.

TABLE B.1.2. Study Use Pattern.

Trial Identification: City, State, EPA Region, Year (Trial No.)	EP[1]	Application Method/ Timing[2]	Growth Stage	Volume[3] (GPA) [L/ha]	Rate (lb ai/A) [g ai/ha]	RTI[4] (days)	Total Rate (lb ai/A) [g ai/ha]	Tank Mix Adjuvants[5]
Clinton, NC, Region 2; 2005 (SJ-HR-05-6270)	Callisto 4.0 SC	1. PSS	00	12.4 [116]	0.25 [275]	NA	0.25 [275]	NA
		2. PSS + POT	Emerged	14.5 [135]	0.25 + 0.094 [278 + 105]	7	0.34 [383]	NIS
		3. POT	Emerged	2.0 [19]	0.094 [106]	NA	0.094 [106]	NIS
Conklin, MI, Region 5; 2005 (NL-HR-05-6271)	Callisto 4.0 SC	1. PSS	Preemergence	16.3 [152]	0.24 [266]	NA	0.24 [266]	NA
		2. PSS + POT	Mature spears	32.9 [308]	0.24 + 0.094 [270 + 105]	13	0.33 [376]	NIS
		3. POT	Mature spears	16.4 [153]	0.094 [106]	NA	0.094 [106]	NIS
Comstock, MI, Region 5; 2005 (NL-HR-05-6272)	Callisto 4.0 SC	1. PSS	Preemergence	16.6 [155]	0.24 [270]	NA	0.24 [270]	NA
		2. PSS + POT	Mature spears	33.3 [311]	0.24 + 0.094 [269 + 105]	14	0.33 [374]	NIS
		3. POT	Mature spears	16.8 [157]	0.095 [106]	NA	0.095 [106]	NIS
Gonzales, CA, Region 10; 2005 (WC-HR-05-6273)	Callisto 4.0 SC	1. PSS	Preemergent	17.6 [165]	0.24 [267]	NA	0.24 [267]	NA
		2. PSS + POT	Market size spears	36.0 [337]	0.24 + 0.094 [270 + 105]	24	0.34 [375]	NIS
		3. POT	Market size spears	17.8 [166]	0.092 [103]	NA	0.092 [103]	NIS

TABLE B.1.2. Study Use Pattern.

Trial Identification: City, State, EPA Region, Year (Trial No.)	EP[1]	Application Method/ Timing[2]	Growth Stage	Volume[3] (GPA) [L/ha]	Rate (lb ai/A) [g ai/ha]	RTI[4] (days)	Total Rate (lb ai/A) [g ai/ha]	Tank Mix Adjuvants[5]
Walnut Grove, CA, Region 10; 2005 (WD-HR-05-6274)	Callisto 4.0 SC	1. PSS	08	19.8 [185]	0.24 [267]	NA	0.24 [267]	NA
		2. PSS + POT	45	39.9 [373]	0.24 + 0.094 [268 + 105]	8	0.33 [373]	NIS
		3. POT	45	20.0 [188]	0.095 [106]	NA	0.095 [106]	NIS
Fire Bough, CA, Region 10; 2005 (WC-HR-05-6275)	Callisto 4.0 SC	1. PSS	Preemergence	20.3 [190]	0.25 [275]	NA	0.25 [275]	NA
		2. PSS + POT	Spears emerging	40.9 [383]	0.25 + 0.097 [280 + 109]	10	0.35 [389]	NIS
		3. POT	Emerging spears	20.1 [188]	0.097 [108]	NA	0.097 [108]	NIS
Hermiston, OR, Region 11; 2005 (WF-HR-05-6277)	Callisto 4.0 SC	1. PSS	00	18.0 [169]	0.24 [274]	NA	0.24 [274]	NA
		2. PSS + POT	9	35.9 [335]	0.25 + 0.092 [274 + 103]	6	0.34 [377]	NIS
		3. POT	9	17.7 [165]	0.092 [102]	NA	0.092 [102]	NIS
Ephrata, WA, Region 11; 2005 (WF-HR-05-6278)	Callisto 4.0 SC	1. PSS	Preemergence	15.2 [142]	0.24 [271]	NA	0.24 [271]	NA
		2. PSS + POT	Spears 2-12" tall	30.0 [281]	0.24 + 0.095 [266 + 106]	8	0.33 [372]	NIS
		3. POT	Spears 2-12" tall	15.3 [143]	0.096 [107]	NA	0.096 [107]	NIS

[1] EP = End-use Product; was formulated as a suspension concentrate containing mesotrione, active ingredient (4.0 lb ai/gal).
[2] PSS = Pre-emergence soil-surface spray application, POT = Post over-the-top application.
[3] GPA = gallons per acre.
[4] Retreatment Interval.
[5] NIS = Non-ionic Surfactant.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Regions	Asparagus		
	Submitted	Requested	
		Canada	U.S.
2	1		1
5	2		2
10	3		3
11	2		2
Total	8		8

B.2. Sample Handling and Preparation

After collection, asparagus spear samples were stored frozen at the field site. Samples remained frozen at the field site until shipment to Syngenta, Greensboro, NC via ACDS freezer truck. Samples were kept under frozen conditions at the laboratory (<-15°C) until further preparation, extraction, and analysis. Asparagus spears were cut into approximately two-inch pieces with a meat cleaver or hand shears. Composited samples were ground in a food cutter, with dry ice used as necessary to keep the sample frozen. After preparation, samples were placed in labeled double polyethylene bags and stored frozen at ≤ -15°C until analyzed.

B.3. Analytical Methodology

Asparagus samples were analyzed for residues of mesotrione using Method RAM 366/01, with the following modifications. A 10-gram sub-sample was Polytron-homogenized for 3-5 minutes with 100 mL of 50% ACN/H_2O (acetonitrile/water) after addition of one gram of sodium chloride (NaCl). Approximately 40 mL of the mixture was centrifuged and an aliquot was taken from the supernatant and diluted with water. The final volume was adjusted with 90% H_2O/methanol (MeOH). The sample final solution was injected onto a LC-MS/MS system for residue analysis. The LOQ was 0.01 ppm for mesotrione for asparagus.

C. RESULTS AND DISCUSSION

Sample storage conditions and intervals are summarized in Table C.2. The maximum storage interval of asparagus samples, from harvest to extraction, was 548 days (18 months). Samples were stored frozen at the field sites for 8-38 days; however temperatures at field sites were not provided. Samples were shipped frozen from the field site to the laboratory, taking anywhere from 0-25 days from date of shipment to date of receipt. Again, temperatures during transit were not reported. At the analytical laboratory, samples were stored frozen at a temperature of <-15°C. Storage stability data indicate mesotrione is stable in asparagus for up to 13 months (refer to 47013801.der). Additional storage stability data indicate mesotrione is stable in corn grain, corn forage, corn fodder, soybean seed, and radish root for up to 40 months. Based on these results, residues of mesotrione are expected to be stable in asparagus for the storage interval of 18 months used in this study. Field sample residues were not corrected for in-storage dissipation.

Asparagus samples were analyzed for residues of mesotrione using modified Method RAM 366/01 with modifications. The samples were analyzed within 1 to 12 days of extraction. The validated LOQ was 0.01 ppm for each analyte in asparagus. Method validation results, apart from concurrent procedural recoveries, were not provided for the method used in this study. Concurrent method recoveries are reported in Table C.1. Concurrent recoveries from controls fortified with mesotrione at 0.01 to 10 ppm ranged from 69% to 110% (average of 86% with a standard deviation of 11.0%, n=21). The average recoveries for mesotrione were in the generally accepted range of 70% to 120%. The fortification levels encompassed the expected residues in asparagus. The method was adequate for data collection based on acceptable concurrent method recoveries.

Residue data from the asparagus field trials are reported in Table C.3. A summary of the residue data for asparagus from the 2-day PHI is presented in Table C.4. At PHIs of 2-3 days, residues of mesotrione ranged from <0.01 to 0.67 ppm. Residues of mesotrione were non-quantifiable (<0.01 ppm) in/on all untreated asparagus samples.

For the residue decline study, data show a general tendency of mesotrione residues to decrease with increasing PHIs.

TABLE C.1. Summary of Concurrent Recoveries of Mesotrione from Asparagus.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± SD* (%)	Overall Mean ± SD (%)
Asparagus	0.01	14	68.8, 70.7, 70.8, 70.9, 73.3, 78.0, 82.1, 87.7, 89.1, 89.5, 93.3, 96.6, 98.0, 110	84.2 ± 12.6	86.4 ± 11.1
	0.05	1	82.2	82.2	
	0.1	2	85.5, 90.5	88.0	
	0.5	1	96.6	96.0	
	1.0	2	91.0, 97.4	94.2	
	10.0	1	93.0	93.0	

* Standard deviations for mean values were not calculated where the number of individual values used to calculate the mean was less than three.

TABLE C.2. Summary of Storage Conditions.

Matrix (RAC)	Analyte	Storage Temperature (°C)	Actual Storage Duration (months)	Interval of Demonstrated Storage Stability* (months)
Asparagus	Mesotrione	<-15°C	13 - 18	13

* Storage stability demonstrated in/on asparagus (refer to 47013801.der).

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; NAFTA Region; Year (Trial No.)	Asparagus Variety	Commodity	Application Method/ Timing	Total Rate (lb ai/A) [g ai/ha]	PHI (days)	Uncorrected Residue Value* (ppm)
Clinton, NC Region 2; 2005 (SJ-HR-05-6270)	Jersey Knight	Spears	PSS	0.25 [275]	NA	<0.01, <0.01
			PSS + POT	0.34 [383]	2	0.05, 0.18
			POT	0.094 [106]	2	0.09, 0.09
Conklin, MI Region 5; 2005 (NL-HR-05-6271)	Centennial	Spears	PSS	0.24 [266]	0	<0.01, <0.01
					1	<0.01, <0.01
					2	<0.01, <0.01
					3	<0.01, <0.01
			PSS + POT	0.33 [376]	0	0.59, 0.66
					1	0.14 (0.16), 0.15 (0.13)
					2	0.09, 0.06
					3	0.05, 0.07
			POT	0.094 [106]	0	0.61, 0.87
					1	0.17 (0.21), 0.21 (0.21)
					2	0.08, 0.06
					3	0.05, 0.04
Comstock, MI Region 5; 2005 (NL-HR-05-6272)	Jersey Giant	Spears	PSS	0.24 [27]	NA	<0.01, <0.01
			PSS + POT	0.33 [374]	2	0.25, 0.21
			POT	0.095 [106]	2	0.35, 0.67
Gonzales, CA Region 10; 2005 (WC-HR-05-6273)	UC157	Spears	PSS	0.24 [267	2	<0.01, <0.01
			PSS + POT	0.34 [375]	2	0.04, 0.03
			POT	0.092 [103]	2	0.05, 0.03
Walnut Grove, CA Region 10; 2005 (WD-HR-05-6274)	UC157	Spears	PSS	0.24 [267]	3	<0.01, <0.01
			PSS + POT	0.33 [373]	3	<0.01, <0.01
			POT	0.095, [106]	3	<0.01, <0.01
Fire Bough, CA Region 10; 2005 (WC-HR-05-6275)	UC157	Spears	PSS	0.25, [275]	2	<0.01, <0.01
			PSS + POT	0.35, [389]	2	0.16, 0.13
			POT	0.097, [108]	2	0.14, 0.13

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; NAFTA Region; Year (Trial No.)	Asparagus Variety	Commodity	Application Method/ Timing	Total Rate (lb ai/A) [g ai/ha]	PHI (days)	Uncorrected Residue Value* (ppm)
Hermiston, OR Region 11; 2005 (WF-HR-05-6277)	Martha Washington	Spears	PSS	0.24, [274]	2	<0.01, <0.01
			PSS + POT	0.34, [377]	2	0.05 (0.04), 0.08 (0.04)
			POT	0.092, [102]	2	0.05 (0.04), 0.03 (0.03)
Ephrata, WA Region 11; 2005 (WF-HR-05-6278)	902-62	Spears	PSS	0.24, [271]	2	<0.01, <0.01
			PSS + POT	0.33, [372]	2	0.04, 0.04
			POT	0.096, [107]	2	0.03, 0.03

LOQ = 0.01 ppm for mesotrione.
* Data in parenthesis are the result of confirmatory analysis.

TABLE C.4. Summary of Residue Data from Crop Field Trials with Mesotrione.

Matrix	Total Application Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels[1] (ppm)						
			n	Min.	Max.	HAFT[2]	Median	Mean	SD
Mesotrione (PSS)									
Asparagus	0.24 – 0.25 [0.266 – 0.275]	NA	16	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Mesotrione (PSS + POT)									
Asparagus	0.33 - 0.35 [0.372 – 0.389]	2-3	16	<0.01	0.25	0.23	0.055	0.088	0.075
Mesotrione (POT)									
Asparagus	0.092 – 0.97 [0.102 – 0.108]	2-3	16	<0.01	0.67	0.51	0.055	0.115	0.169

[1] LOQ = 0.01 ppm for mesotrione.
[2] HAFT = Highest-Average Field Trial.

D. CONCLUSION

The submitted field trial data are adequate and reflect the use of three foliar applications of the Callisto® 4SC formulation of mesotrione at total rates of 0.094 to 0.334 lb ai/A on asparagus grown in the United States with a 2-day PHI. An acceptable method was used for quantitation of residues in/on asparagus based on untreated control sample spike recoveries.

Asparagus samples were stored frozen prior to analysis; the maximum storage interval from harvest to extraction was 18 months. Sample storage intervals between sampling, extraction and analysis ranged from 13 to 18 months. Mesotrione residues were found to be stable in asparagus under freezer storage conditions for at least 13 months (refer to 47013801.der). In addition, residues of mesotrione were found to be stable in corn grain, corn forage, corn fodder, soybean seed, and radish root for up to 40 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477). Based on these results, residues of mesotrione are expected to be stable in asparagus over the storage interval of 18 months for this study.

Residues of mesotrione treated by PSS spray only at a total rate of 0.24 lbs ai/A were less than the LOQ (0.01 ppm) in all samples. A PHI was not applicable.

The maximum residue of mesotrione was 0.25 ppm in/on asparagus harvested 2 days after PSS

spray application followed by a POT spray (at a total rate of 0.334 lbs ai/A). The maximum residue of mesotrione was 0.67 ppm in/on asparagus harvested 2 days after POT spray only (at a total rate of 0.094 lbs ai/A). Residue decline data show that mesotrione residues generally decrease with increasing PHIs. Analysis of untreated control samples demonstrated that residues were less then the LOQ (0.01 ppm).

E. REFERENCES

DP#s: 245477 and 260267
Subject: PP#: 8F04954. Mesotrione in/on Field Corn. Evaluation of Residue Data and Analytical Methods. PC Code: 122990. DP Barcodes: D245477, and D260267. Case #: 289589. Submission #s: S541377, and S569871. MRID #s: 44505118, 44505212-23, 44537109-12, 44901719, and 44942401-03.
From: Sarah Levy
To: Jim Stone/Jim Tompkins
Date: 06-JUN-2001
MRID#: 47136802

DP#: 283827
Subject: Mesotrione. Summary of Analytical Chemistry and Residue Data for Sweet Corn, PP#2F06443, and Response to Data Deficiencies of a Previous HED Review (PP#8F04954, DP Barcodes: D245477 and D260267, 6/6/01, S. Levy).
From: William Cutchin
To: J. Stone/J. Miller
Date: 12-JAN-2005
MRID#: 45651803

DP#: 263245
Subject: Product Chemistry Review of Mesotrione (ZA 1296 Technical (dry)).
From: H. Podall
To: J. Tompkins/J. Stone
Date: 24-FEB-2000
MRID#s: 44373503-44373505, 44505003, 44505004, and 44901701

F. DOCUMENT TRACKING

RDI: G.F. Kramer (05-DEC-2007), RAB1 Chemists (26-SEP-2007)
S. Levy:S10953:PY1:(703)305-0783:7509P:RAB1
Petition #: 6F7162
DP#: 338109
PC Code: 122990

Template Version June 2005

Mesotrione/ZA1296/ PC Code 122990/Sygenta Crop Protection
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial/Residue Decline – Grasses grown for seed

Primary Evaluator: Date: 05-DEC-2007
Sarah J. Levy, Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509P)

Approved by: Date: 05-DEC-2007
George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)

Note: This data-evaluation record (DER) was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 29-JUN-2007). The DER has been reviewed by HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

MRID#: 47013803. Lin, K. (2006). Mesotrione: Magnitude of the Residue in or on Grasses Grown-for-Seed (From Grass, Forage, Fodder and Hay, Group 17). Lab Project Number: T021570-04. Unpublished study prepared by Syngenta Crop Protection, Inc. 122 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection has submitted field trial data for mesotrione on grasses grown for seed. Nine field trials were conducted in the U.S. during the 2005 growing season in Regions 5 (KS, MN, and MO; 3 trials), 10 (CA; 1 trial), 11 (ID and WA; 2 trials), and 12 (OR; 3 trials). The grass commodities from one field trial (MN; Region 5) were lost due to chemical phytotoxicity.

At each trial location, grasses were treated with the 4 lb/gal suspension concentrate (SC) formulation using one of the two following treatment regimes: (i) a single post-emergence foliar broadcast spray at 0.184-0.192 lb ai/A (Treatment Regime No. 2); or (ii) two post-emergence foliar broadcast spray applications, the first application at ~0.187 lb ai/A followed by a second application at ~0.094 lb ai/A, for a total rate of 0.273-0.287lb ai/A (Treatment Regime No. 3). An adjuvant (crop-oil concentrate (COC)) was added to the spray mixture, and applications were made in ~2-30 gallons/A (GPA) of water using ground equipment. For Treatment Regime No. 2, a single application was made 60 days prior to harvest of mature seeds and straw, and regrowth of forage and hay were collected 14 days after harvest of mature seeds and straw at a 74-day pre-harvest interval (PHI). For Treatment Regime No. 3, seeds and straw were harvested 30 days after the last application, and regrowth forage and hay were collected 14 days after harvest of mature seeds and straw at a 44-day PHI. Additional samples of regrowth forage and hay were collected at 7, 14, and 21 days after harvest of seed from both treatments to generate residue decline data.

Samples of grass seed, straw, regrowth forage, and regrowth hay were analyzed for residues of mesotrione using method RAM 366/01 (liquid chromatography with tandem mass-spectrometry detectors (LC-MS/MS)). This method was previously reviewed and forwarded to the U.S. Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual Volume II (PAM Vol. II) as a confirmatory enforcement method for plant commodities (Memo, W.

Cutchin, 12-JAN-2005; DP#: 283827). The method is adequate for data collection based on acceptable concurrent recovery data. The validated limit of quantitation (LOQ) was 0.01 ppm for mesotrione in/on grass matrices.

The maximum storage duration of grass samples from harvest to analysis was 301 days (~10 months). The petitioner referenced available storage stability data which demonstrate that mesotrione is stable in corn matrices and soybean seed stored frozen for up to 40-42 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477). The available corn and soybean storage stability data will support the storage conditions and durations of samples from the subject grass field trials.

Maximum residues of mesotrione were 0.09 ppm in/on samples of grass straw and seed screenings harvested 60 days following a single post-emergence foliar broadcast application of the 4 lb/gal SC formulation at 0.184-0.192 lb ai/A (Treatment Regime No. 2). Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of grass forage and hay harvested 74 days following Treatment Regime No. 2.

Maximum residues of mesotrione were 3.30 ppm in/on samples of grass straw and 2.70 ppm in/on samples of seed screenings harvested 30 days following the last of two post-emergence foliar broadcast applications of the 4 lb/gal SC formulation at a total rate of 0.273-0.287 lb ai/A (Treatment Regime No. 3). Residues of mesotrione were at or below the LOQ (<0.01 ppm) in/on all samples of grass forage and hay harvested 44 days following Treatment Regime No. 3.

In the residue decline studies, following Treatment Regime No. 2, residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of regrowth forage and hay. Following Treatment Regime No. 3, low quantifiable residues of mesotrione were observed at the 37-day PHI in samples of regrowth forage (0.01 ppm) and hay (0.02 ppm), but residues declined to below the LOQ (<0.01 ppm) by the 51-day PHI.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the grass residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP#: 338109].

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Mesotrione is a triketone herbicide which inhibits the enzyme *p*-hydroxyphenylpyruvate dioxygenase (HPPD), disrupting carotenoid biosynthesis. This process leads to the destruction

of chlorophyll, resulting in a bleaching effect in susceptible plants. Mesotrione is intended for preemergence and postemergence use for selective control of annual broadleaf weeds in field, pop, and sweet corn. The nomenclature of mesotrione is summarized in Table A.1, and the physicochemical properties of mesotrione are summarized in Table A.2.

TABLE A.1. Mesotrione Nomenclature.

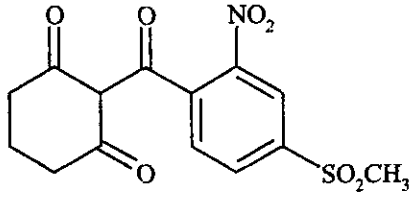
Chemical structure	
Common name	Mesotrione
Company experimental name	ZA1296
IUPAC name	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
CAS name	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
CAS registry number	104206-82-8
End-use product (EP)	4 lb/gal SC (Callisto® Herbicide; EPA Reg. No. 100-1131)

TABLE A.2. Physicochemical Properties of Mesotrione.

Parameter	Value	Reference
Melting range	148.7-152.5°C	RD Memo, H. Podall, 24-FEB-2000; DP#: 263245.
pH	3.4 (1% dispersion in water; 25°C)	
Density	1.46 g/mL, 20°C	
Water solubility	20°C 160 ppm, unbuffered water 0.22 g/100 mL, pH 4.8 1.5 g/100mL, pH 6.9 2.2 g/100 mL, pH 9	
Solvent solubility	20°C 0.37 g/100 mL, methanol 1.7 g/100 mL, ethyl acetate 0.27 g/100 mL, toluene 10.4 g/100 mL, acetonitrile <0.03 g/100 mL, heptane 8.1 g/100 mL, acetone	
Vapor pressure	4.3 x 10^{-8} torr, 20°C	
Dissociation constant, pK_a	3.12, 20°C	
Octanol/water partition coefficient, Log(K_{OW})	20°C log P_{OW} = 0.11 in unbuffered water log P_{OW} = 0.90 in pH 5 buffer log P_{OW} <-1 at pH 7 and 9 buffered water	
UV/visible absorption spectrum	Absorption maximum in methanol at 256 mu, with a molar extinction coefficient of 2.24 x 104 M cm.	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Nine field trials were conducted in the U.S. during the 2005 growing season in Regions 5 (KS, MN, and MO; 3 trials), 10 (CA; 1 trial), 11 (ID and WA; 2 trials), and 12 (OR; 3 trials). The grass commodities from one field trial (MN; Region 5) were lost due to chemical phytotoxicity.

Each trial site consisted of one untreated plot (Treatment Regime No. 1) and two treated plots (Treatment Regimes Nos. 2 and 3). At each trial location, grasses were treated with the 4 lb/gal SC formulation using one of the two treatment regimes: (i) a single post-emergence foliar broadcast spray at ~0.187 lb ai/A (Treatment Regime No. 2); or (ii) two post-emergence foliar broadcast spray applications, the first application at ~0.187 lb ai/A followed by a second application at ~0.094 lb ai/A, for a total rate of ~0.281 lb ai/A (Treatment Regime No. 3). An adjuvant (COC) was added to the spray mixture, and applications were made in ~2-30 gal/A of water using ground equipment. For Treatment Regime No. 2, a single application was made 60 days prior to harvest of mature seeds and straw and regrowth of forage and hay were collected 14 days after harvest of mature seeds and straw at a 74-day PHI. For Treatment Regime No. 3, seeds and straw were harvested 30 days after the last application and regrowth forage and hay were collected 14 days after harvest of mature seeds and straw at a 44-day PHI. Additional samples of regrowth forage and hay were collected at 7, 14, and 21 days after harvest of seed the both treatments to generate residue decline data.

Grasses were grown under normal agricultural conditions. The petitioner reported cultural practices and maintenance pesticides and fertilizers used at each site. Trial site conditions are presented in Table B.1.1. The crop varieties grown are identified in Table C.3. The petitioner included the overall monthly rainfall and temperature ranges for each trial site and stated that actual temperatures and rainfall amounts were within the average historical ranges at all trial sites. Irrigation was used to supplement rainfall as needed.

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State; Year (Trial ID)	Soil characteristics[1]			
	Type	%OM	pH	CEC (meq/g)
Memphis, MO; 2005 (ND-HR-05-6325)	Silty Clay Loam	4.88	6.24	14.0
Troy, KS; 2005 (ND-HR-05-6326)	Silty Loam	2.6	5.8	14.2
Brawley, CA; 2005 (WA-HR-05-6328)	Clay	1.8	8.0	26.6
Raft River, ID; 2005 (WG-HR-05-6329)	Loam	1.9	8.3	29.7
White Swan, WA; 2005 (WF-HR-05-6330)	Silt Loam	2.3	7.1	19.6
Amity, OR; 2005 (WG-HR-05-6331)	Silty Clay Loam	4.4	5.2	16.6
Hillsboro, OR; 2005 (WG-HR-05-6332)	Silty Loam	4.4	8.2	39.1
Forest Grove, OR; 2005 (WG-HR-05-6333)	Loam	4.4	7.3	21.8

[1] OM = organic matter; CEC = cation-exchange capacity.

TABLE B.1.2. Study Use Pattern.

Trial Identification: City, State; Year (Trial ID)	EP[1]	Application						Tank Mix/ Adjuvants
		Trtmt No.[2]	Method; Timing	Volume[3] (GPA)	Rate (lb ai/A)	RTI[4] (days)	Total Rate (lb ai/A)	
Memphis, MO; 2005 (ND-HR-05-6325)	4 lb/gal SC	2	1. Post-emergence foliar broadcast spray; BBCH 45-47	27	0.192	--	0.192	COC[5] 1.00% v:v
		3	1. Post-emergence foliar broadcast spray; BBCH 45-47	27	0.192	--	0.286	COC 1.00% v:v
			2. Post-emergence foliar spray; BBCH 80	15	0.094	33		COC 1.00% v:v
Troy, KS; 2005 (ND-HR-05-6326)	4 lb/gal SC	2	1. Post-emergence foliar broadcast spray; preboot to headed	2	0.192	--	0.192	COC 1.00% v:v
		3	1. Post-emergence foliar broadcast spray; preboot to headed	2	0.191	--	0.287	COC 1.00% v:v
			2. Post-emergence foliar spray; dough	2	0.096	29		COC 1.00% v:v
Brawley, CA; 2005 (WA-HR-05-6328)	4 lb/gal SC	2	1. Post-emergence foliar broadcast spray; 30% headed	20	0.189	--	0.189	COC 1.00% v:v
		3	1. Post-emergence foliar broadcast spray; 30% headed	20	0.185	--	0.279	COC 1.00% v:v
			2. Post-emergence foliar spray; month before harvest	30	0.094	30		COC 1.00% v:v
Raft River, ID; 2005 (WG-HR-05-6329)	4 lb/gal SC	2	1. Post-emergence foliar broadcast spray; stem 10% of final length	14	0.188	--	0.188	COC 1.00% v:v
		3	1. Post-emergence foliar broadcast spray; stem 10% of final length	14	0.189	--	0.286	COC 1.00% v:v
			2. Post-emergence foliar spray; beginning of heading	12	0.097	29		COC 1.00% v:v
White Swan, WA; 2005 (WF-HR-05-6330)	4 lb/gal SC	2	1. Post-emergence foliar broadcast spray; early bloom	20	0.184	--	0.184	COC 1.00% v:v
		3	1. Post-emergence foliar broadcast spray; early bloom	20	0.184	--	0.273	COC 1.00% v:v
			2. Post-emergence foliar spray; seed formation	22	0.089	31		COC 1.00% v:v
Amity, OR; 2005 (WG-HR-05-6331)	4 lb/gal SC	2	1. Post-emergence foliar broadcast spray; BBCH 47	20	0.186	--	0.186	COC 1.00% v:v
		3	1. Post-emergence foliar broadcast spray; BBCH 47	20	0.187	--	0.280	COC 1.00% v:v
			2. Post-emergence foliar spray; BBCH 67	20	0.093	30		COC 1.00% v:v
Hillsboro, OR; 2005 (WG-HR-05-6332)	4 lb/gal SC	2	1. Post-emergence foliar broadcast spray; BBCH 40	14	0.188	--	0.188	COC 1.00% v:v
		3	1. Post-emergence foliar broadcast spray; BBCH 40	13	0.185	--	0.278	COC 1.00% v:v

TABLE B.1.2. Study Use Pattern.

Trial Identification: City, State; Year (Trial ID)	EP[1]	Application						Tank Mix/ Adjuvants
		Trtmt No.[2]	Method; Timing	Volume[3] (GPA)	Rate (lb ai/A)	RTI[4] (days)	Total Rate (lb ai/A)	
			2. Post-emergence foliar spray; BBCH 65	14	0.093	30		COC 1.00% v:v
Forest Grove, OR; 2005 (WG-HR-05-6333)	4 lb/gal SC	2	1. Post-emergence foliar broadcast spray; 10% head emergence	18	0.185	--	0.185	COC 1.00% v:v
		3	1. Post-emergence foliar broadcast spray; 10% head emergence	18	0.190	--	0.285	COC 1.00% v:v
			2. Post-emergence foliar spray; 30 days prior to harvest	18	0.095	29		COC 1.00% v:v

[1] EP = End-use Product; Callisto ® 4SC Herbicide (EPA Reg. No. 100-1131).
[2] Treatment Regime No. 2 = Single post-emergence foliar broadcast application and Treatment Regime No. 3 = Two post-emergence foliar broadcast spray applications.
[3] GPA = gallons per acre.
[4] RTI = Retreatment Interval.
[5] COC = Crop-Oil Concentrate.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Regions	Grass		
	Submitted	Requested	
		Canada	U.S.
5	2[1]		3
10	1		
11	2		2
12	3		3
Total	8		8

[1] An additional trial was conducted in MN (Region 5); however, the grass commodities were lost because of chemical phytotoxicity.

B.2. Sample Handling and Preparation

One control and duplicate treated samples of grass straw (~2 lbs) and seed samples were collected at maturity (60-day PHI for Treatment Regime No. 2 and 30-day PHI for Treatment Regime No. 3). Regrowth forage (~3 lbs) and hay (~2 lbs) were collected 14 days after the harvest of mature seed for both treatment regimes. Enough seeds were threshed to generate 0.5-1 lb of seed screenings. Additional samples of regrowth forage and hay were collected at 7, 14, and 21 days after harvest of seed the both treatments to generate residue decline data.

All samples were placed in frozen storage at the field sites, and were shipped frozen via Agricultural Chemicals Development Service (ACDS) truck to Syngenta Crop Protection (Greensboro, NC) for residue analysis. Samples were stored frozen (~-15°C) at the analytical laboratory until preparation for extraction/analysis. Samples of forage, hay and straw were prepared by cutting into 2" pieces with meat cleaver or hand shears in the presence of dry ice.

B.3. Analytical Methodology

Samples of grass commodities were analyzed for residues of mesotrione using LC-MS/MS method, RAM 366/01, entitled "Residue Analytical Method for the Determination of Residues of Mesotrione and 4-(Methylsufonyl)-2-Nitrobenzoic Acid (MNBA) in Crop Samples." A detailed description of the method was not included in the study report. This method has been previously reviewed and was forwarded to FDA for inclusion in PAM Vol. II as a confirmatory enforcement method for plant commodities (Memo, W. Cutchin 12-JAN-2005; DP#: 283827).

Briefly, homogenized samples were mixed with sodium chloride (10:1, wt:wt) and extracted with acetonitrile (ACN):water (1:1, v:v). An aliquot of the extract was diluted with water and the final volume adjusted with 90% water/methanol (MeOH) for LC-MS/MS analysis. The monitored ion transition was m/z 338 → 291. The validated LOQ was 0.01 ppm. The limit of detection (LOD), as determined by the smallest amount of analyte injected, was 0.001 ng of mesotrione.

C. RESULTS AND DISCUSSION

Sample storage conditions and durations are summarized in Table C.2. Storage durations of grass samples from harvest to analysis were 90-293 days (3.0-9.6 months) for straw, 119-293 days (3.9-9.6 months) for seed screenings, 196-236 days (6.4-7.8 months) for forage, and 203-301 days (6.7-9.9 months) for hay. The petitioner referenced available storage stability data which demonstrate that mesotrione is stable in corn matrices and soybean seed stored frozen for up to 40-42 months (PP#8F04954; DP#s 245477 and 260267, 6/6/01, S. Levy). The available corn and soybean storage stability data will support the storage conditions and durations of samples from the subject grass field trials.

Samples of grass straw, seed screenings, forage, and hay were analyzed for residues of mesotrione using LC-MS/MS method RAM 366/01. This method was previously reviewed and forwarded to FDA for inclusion in PAM Vol. II as a confirmatory enforcement method for plant commodities (refer to DP# 283827, 1/12/05, W. Cutchin). The validated LOQ was 0.01 ppm for mesotrione in/on grasses. Method recoveries from concurrent analysis of samples (see Table C.1) are generally within the acceptable range of 70-120%, except for one sample of grass hay fortified with mesotrione at 0.01 ppm, which resulted in a recovery of 69%. Adequate sample calculations and chromatograms were provided. Apparent residues of mesotrione were below the LOQ in/on eight untreated samples each of grass straw and seed screenings, and in/on seven samples each of untreated grass forage and hay.

Residue data from the grass field trials are reported in Table C.3. A summary of the residue data for grass straw, seed screenings, forage, and hay is presented in Table C.4. Residues of mesotrione were below the LOQ (<0.01 ppm) to 0.09 ppm in/on samples of grass straw and seed screenings harvested 60 days following a single post-emergence foliar broadcast application of the 4 lb/gal SC formulation at 0.184-0.192 lb ai/A (Treatment Regime No. 2). Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of grass forage and hay

harvested 74 days following Treatment Regime No. 2. Residues of mesotrione were below the LOQ (<0.01 ppm) to 3.30 ppm in/on samples of grass straw and below the LOQ (<0.01 ppm) to 2.70 ppm in/on samples of seed screenings harvested 30 days following the last of two post-emergence foliar broadcast applications of the 4 lb/gal SC formulation at a total rate of 0.273-0.287 lb ai/A (Treatment Regime No. 3). Residues of mesotrione were at or below the LOQ (<0.01 ppm) in/on all samples of grass forage and hay harvested 44 days following Treatment Regime No. 3.

In the residue decline studies, following Treatment Regime No. 2, residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples regrowth forage and hay. Following Treatment Regime No. 3, low quantifiable residues of mesotrione were observed at the 37-day PHI in samples of regrowth forage (0.01 ppm) and hay (0.02 ppm), but residues declined to below the LOQ (<0.01 ppm) by the 51-day PHI.

TABLE C.1. Summary of Concurrent Recoveries of Mesotrione from Grass Matrices.

Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± S.D.[1] (%)
Forage	0.01	5	77, 80, 83, 83, 96	84 ± 7
	0.05	1	71	71
	0.1	2	85, 85	85
	0.5	1	84	84
	Total	**9**	**71-96**	**83 ± 7**
Hay	0.01	6	69, 71, 72, 79, 83, 87	77 ± 7
	0.02	1	91	91
	0.5	1	73	73
	1	1	91	91
	Total	**9**	**69-91**	**80 ± 9**
Straw	0.01	7	71, 72, 73, 73, 75, 76, 77	74 ± 2
	0.02	1	78	78
	0.2	2	70, 79	75
	Total	**10**	**70-79**	**74 ± 3**
Seed screenings	0.01	4	71, 81, 111, 118,	95 ± 23
	0.05	3	71, 73, 83	76 ± 6
	0.1	1	100	100
	1	2	74, 84	79
	5	1	101	101
	Total	**11**	**71-118**	**88 ± 17**

[1] S.D. is applicable only for groups ≥ 3 samples.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability[2]
Grass straw	- 15	90-293 days (3.0-9.6 months)	Residues of mesotrione are relatively stable in/on fortified soybean seed and corn matrices (forage, stover and grain) stored frozen for 40-42 months.
Grass seed screenings		119-293 days (3.9-9.6 months)	
Grass forage		196-236 days (6.4-7.8 months)	
Grass hay		203-301 days (6.7-9.9 months)	

[1] *Duration from harvest to analysis. All samples were analyzed within 8 days of extraction.*
[2] See Memo, S. Levy, 016-JUN-2001; DP#: 245477.

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial ID)	*Region*	*Crop;* Variety	Commodity or Matrix	Total Rate (lb ai/A)	PHI (days)	Mesotrione Residues (ppm)
Treatment Regime No. 2: Single post-emergence foliar broadcast application						
Memphis, MO; 2005 (ND-HR-05-6325)	5	Grass; Kentucky 31	Straw	0.192	60	<0.01, <0.01
			Seed Screenings	0.192	60	<0.01, <0.01
			Forage regrowth	0.192	67	<0.01, <0.01
					74	<0.01, <0.01
					81	<0.01, <0.01
			Hay regrowth	0.192	67	<0.01, <0.01
					74	<0.01, <0.01
					81	<0.01, <0.01
Troy, KS; 2005 (ND-HR-05-6326)	5	Grass; Unknown	Straw	0.192	60	<0.01, <0.01
			Seed Screenings	0.192	60	<0.01, <0.01
			Forage regrowth	0.192	74	<0.01, <0.01
			Hay regrowth	0.192	74	<0.01, <0.01
Brawley, CA; 2005 (WA-HR-05-6328)	10	Grass; Senesta	Straw	0.189	60	0.04[1], 0.09[1]
			Seed Screenings	0.189	60	0.09[1], 0.08[1]
Raft River, ID; 2005 (WG-HR-05-6329)	11	Grass; Mixed[2]	Straw	0.188	60	<0.01, <0.01
			Seed Screenings	0.188	60	<0.01, <0.01
			Forage regrowth	0.188	74	<0.01, <0.01
			Hay regrowth	0.188	74	<0.01, <0.01
White Swan, WA; 2005 (WF-HR-05-6330)	11	Grass; Pro AM	Straw	0.184	60	<0.01, <0.01
			Seed Screenings	0.184	60	0.01[1], <0.01[1]
			Forage regrowth	0.184	74	<0.01, <0.01
			Hay regrowth	0.184	74	<0.01, <0.01
Amity, OR; 2005 (WG-HR-05-6331)	12	Grass; Warrior	Straw	0.186	60	<0.01, <0.01
			Seed Screenings	0.186	60	<0.01, <0.01
			Forage regrowth	0.186	74	<0.01, <0.01
			Hay regrowth	0.186	74	<0.01, <0.01
Hillsboro, OR; 2005	12	Grass;	Straw	0.188	60	<0.01, <0.01

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial ID)	Region	Crop; Variety	Commodity or Matrix	Total Rate (lb ai/A)	PHI (days)	Mesotrione Residues (ppm)
(WG-HR-05-6332)		Applaud	Seed Screenings	0.188	60	<0.01, <0.01
			Forage regrowth	0.188	74	<0.01, <0.01
			Hay regrowth	0.188	74	<0.01, <0.01
Forest Grove, OR; 2005 (WG-HR-05-6333)	12	Grass; Rebel Exceda	Straw	0.185	60	<0.01, <0.01
			Seed Screenings	0.185	60	<0.01, <0.01
			Forage regrowth	0.185	74	<0.01, <0.01
			Hay regrowth	0.185	74	<0.01, <0.01
Treatment Regime No. 3: Two post-emergence foliar broadcast spray applications						
Memphis, MO; 2005 (ND-HR-05-6325)	5	Grass; Kentucky 31	Straw	0.286	30	0.23[1], 0.31[1]
			Seed Screenings	0.286	30	0.81[1], 0.74[1]
			Forage regrowth	0.286	37	0.01, <0.01
					44	0.01, 0.01
					51	<0.01, <0.01
			Hay regrowth	0.286	37	0.02, 0.02
					44	0.01, 0.01
					51	<0.01, <0.01
Troy, KS; 2005 (ND-HR-05-6326)	5	Grass; Unknown	Straw	0.287	30	<0.01, <0.01
			Seed Screenings	0.287	30	0.05[1], 0.05[1]
			Forage regrowth	0.287	44	<0.01, <0.01
			Hay regrowth	0.287	44	<0.01, <0.01
Brawley, CA; 2005 (WA-HR-05-6328)	10	Grass; Senesta	Straw	0.279	30	3.3[1], 2.6[1]
			Seed Screenings	0.279	30	2.7[1], 2.4[1]
Raft River, ID; 2005 (WG-HR-05-6329)	11	Grass; Mixed[2]	Straw	0.286	30	<0.01, <0.01
			Seed Screenings	0.286	30	<0.01, 0.01
			Forage regrowth	0.286	44	<0.01, <0.01
			Hay regrowth	0.286	44	<0.01, <0.01
White Swan, WA; 2005 (WF-HR-05-6330)	11	Grass; Pro AM	Straw	0.273	30	0.12, 0.11
			Seed Screenings	0.273	30	0.34[1], 0.07[1]
			Forage regrowth	0.273	44	<0.01, <0.01
			Hay regrowth	0.273	44	<0.01, <0.01
Amity, OR; 2005 (WG-HR-05-6331)	12	Grass; Warrior	Straw	0.280	30	0.03, 0.03
			Seed Screenings	0.280	30	0.01, 0.03
			Forage regrowth	0.280	44	<0.01, <0.01
			Hay regrowth	0.280	44	<0.01, <0.01
Hillsboro, OR; 2005 (WG-HR-05-6332)	12	Grass; Applaud	Straw	0.278	30	0.03, <0.01
			Seed Screenings	0.278	30	0.02, 0.01
			Forage regrowth	0.278	44	<0.01, <0.01
			Hay regrowth	0.278	44	<0.01, <0.01
Forest Grove, OR; 2005 (WG-HR-05-6333)	12	Grass; Rebel Exceda	Straw	0.285	30	<0.01, <0.01
			Seed Screenings	0.285	30	<0.01, 0.01
			Forage regrowth	0.285	44	<0.01, <0.01
			Hay regrowth	0.285	44	<0.01, <0.01

[1] Replicate analysis of a single sample; the highest residue is reported.

[2] 30% Adelphi, 22% Quantum Leap, 21% Award, 21% New Blade, and 5% Midnight.

TABLE C.4. Summary of Residue Data from Crop Field Trials with Mesotrione.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT[1]	Median	Mean	S.D.
Treatment Regime No. 2: Single post-emergence foliar broadcast application of the 4 lb/gal SC formulation									
Grass straw	0.184-0.192	60	16	<0.01	0.09	0.07	0.01	0.01	0.02
Grass seed screenings	0.184-0.192	60	16	<0.01	0.09	0.09	0.01	0.02	0.03
Grass forage	0.184-0.192	74	14	<0.01	<0.01	<0.01	<0.01	<0.01	--
Grass hay	0.184-0.192	74	14	<0.01	<0.01	<0.01	<0.01	<0.01	--
Treatment Regime No. 3: Two post-emergence foliar broadcast spray applications of the 4 lb/gal SC formulation									
Grass straw	0.273-0.287	30	16	<0.01	3.30	2.95	0.03	0.43	1.00
Grass seed screenings	0.273-0.287	30	16	<0.01	2.70	2.55	0.04	0.45	0.86
Grass forage	0.273-0.287	44	14	<0.01	0.01	0.01	<0.01	<0.01	--
Grass hay	0.273-0.287	44	14	<0.01	0.01	0.01	<0.01	<0.01	--

[1] HAFT = Highest-Average Field Trial.

D. CONCLUSION

The submitted field trial data are acceptable and reflect either a single post-emergence foliar broadcast spray application of the 4 lb/gal SC formulation at 0.184-0.192 lb ai/A, or two post-emergence foliar broadcast spray applications at a total rate of 0.273-0.287 lb ai/A. An acceptable method was used for quantitation of residues in/on grass commodities, and adequate data are available to support sample storage durations and conditions.

Maximum residues of mesotrione were 0.09 ppm in/on samples of grass straw and seed screenings harvested 60 days following a single post-emergence foliar broadcast application of the 4 lb/gal SC formulation at 0.184-0.192 lb ai/A (Treatment Regime No. 2). Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of grass forage and hay harvested 74 days following Treatment Regime No. 2.

Maximum residues of mesotrione were 3.30 ppm in/on samples of grass straw and 2.70 ppm in/on samples of seed screenings harvested 30 days following the last of two post-emergence foliar broadcast applications of the 4 lb/gal SC formulation at a total rate of 0.273-0.287 lb ai/A (Treatment Regime No. 3). Residues of mesotrione were at or below the LOQ (<0.01 ppm) in/on all samples of grass forage and hay harvested 44 days following Treatment Regime No. 3.

In the residue decline studies, following Treatment Regime No. 2, residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples regrowth forage and hay. Following Treatment Regime No. 3, low quantifiable residues of mesotrione were observed at the 37-day PHI in samples of regrowth forage (0.01 ppm) and hay (0.02 ppm), but residues declined to below the LOQ (<0.01 ppm) by the 51-day PHI.

E. REFERENCES

DP#s: 245477 and 260267
Subject: PP#: 8F04954. Mesotrione in/on Field Corn. Evaluation of Residue Data and Analytical Methods. PC Code: 122990. DP Barcodes: D245477, and D260267. Case #: 289589. Submission #s: S541377, and S569871. MRID #s: 44505118, 44505212-23, 44537109-12, 44901719, and 44942401-03.
From: Sarah Levy
To: J.Stone/J.Tompkins
Date: 06-JUN-2001
MRID#: 47136802

DP#: 283827
Subject: Mesotrione. Summary of Analytical Chemistry and Residue Data for Sweet Corn, PP#2F06443, and Response to Data Deficiencies of a Previous HED Review (PP#8F04954, DP Barcodes: D245477 and D260267, 6/6/01, S. Levy).
From: William Cutchin
To: J. Stone/J. Miller
Date: 12-JAN-2005
MRID#: 45651803

DP#: 263245
Subject: Product Chemistry Review of Mesotrione (ZA 1296 Technical (dry)).
From: H. Podall
To: J. Tompkins/J. Stone
Date: 24-FEB-2000
MRID#s: 44373503-44373505, 44505003, 44505004, and 44901701

F. DOCUMENT TRACKING

RDI: G.F. Kramer (05-DEC-2007), RAB1 Chemists (03-OCT-2007)
S. Levy:S10953:PY1:(703)305-0783:7509P:RAB1
Petition #: 6F7162
DP#: 338109
PC Code: 122990

Template Version June 2005

Mesotrione/ZA01296/Syngenta Crop Protection, Inc.
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial/Residue Decline – Okra

Primary Evaluator: Date: 05-DEC-2007
Sarah J. Levy, Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509P)

Approved by: Date: 05-DEC-2007
George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)

Note: This data-evaluation record (DER) was originally prepared by Tetrahedron, Inc, subcontractor for Versar, Inc. (6850 Versar Center, Springfield, VA 22151; submitted 31-MAY-2007). The DER has been reviewed by the HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORTS:

MRID#: 47013804. Lin, K. (2006). Mesotrione - Magnitude of the Residues in or on Okra. Lab Project Number: T021571-04, Task Number: T021571-04. Unpublished study prepared by Syngenta Crop Protection, Inc. 77 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted field trial data for mesotrione in/on okra. Five field trials (four harvest and one decline) were conducted in the U.S. encompassing Regions 2 (1 trial in NC), 3 (1 trial in FL), 4 (1 trial in MS), and 6 (1 trial in TX and 1 trial in OK) during the 2005 growing season. At each trial location, there was one untreated and five treated plots.

The treated plots were treated with Callisto® 4SC, a formulation of mesotrione, using one of the five following treatment regimes: (1) preemergence soil-surface (PSS) spray at a rate of 0.196-0.205 lbs ai/A (0.22-0.23 kg ai/ha); (2) PSS spray followed by a post-emergence over-the-top (POT) spray for a total rate of 0.285-0.301 lbs ai/A (0.32-0.38 kg ai/ha); (3) PSS spray followed by a post-emergence direct (PD) application for a total rate of 0.293-0.300 lbs ai/A (0.33-0.34 kg ai/ha); (4) POT spray at 0.093-0.097 lbs ai/A (0.105-0.109 kg ai/ha); and (5) PD application at 0.086-0.096 lbs ai/A (0.097-0.107 kg ai/ha). Total treatment regime volumes ranged from 4-50 gallons/Acre (GPA) (37-466 L/ha). An adjuvant (0.25% (v:v) nonionic surfactant (NIS)) was added to the spray mixture for treatment regimes 2 through 5.

For each of the field trials, one untreated and two treated mature okra pods raw agricultural commodity (RAC) samples were collected after each of the various spraying regimes. For treatment regimes including POT treatment, samples were collected 45 days after application [45 day pre-harvest interval (PHI)]. For treatment regimes including PD application, samples were collected at 28 day PHI. It should be noted that the PHIs were considered not applicable for those treated by PSS only. In the decline trial (SA-HR-05-6263), okra pods were collected at 0, 15, 30, 45 and 52 days for samples incorporating treatment by POT spray, and 0, 14, 21, 28, and 35 days for samples incorporating treatment by PD application.

Okra pod samples were analyzed for residues of mesotrione using Method RAM 366/01 (liquid chromatography with tandem mass-spectrometry detectors (LC-MS/MS)) with modifications.

The method was adequate for data collection based on acceptable concurrent method recoveries.

Okra samples were stored frozen prior to analysis; the maximum storage interval from harvest to extraction was 13 months. Storage intervals between sampling, extraction and analysis ranged from 11 to 13 months. Mesotrione residues were found to be stable in okra under freezer storage conditions for at least 13 months (refer to 47013801.der). Based on these results, residues of mesotrione are expected to be stable in okra over the storage interval of this study.

Residues of mesotrione in okra harvested after PSS spray only were less than the LOQ (0.01 ppm) in all samples. Residues of mesotrione in okra harvested 45 days after the final treatment for the PSS+POT treatment regime and the POT only treatment regime were less than the LOQ (0.01 ppm) in all samples. Residues of mesotrione in okra harvested 28 days after the final treatment for the PSS+PD treatment regime and the PD only treatment regime were less than the LOQ (0.01 ppm) in all samples.

In the decline trial, all residues in the okra samples were <0.01 ppm, except for the samples harvested at day 0 for the PSS+POT treatment regime (0.09 and 0.2 ppm) and the POT only treatment regime (0.19 ppm and 0.16 ppm). Residue decline data show that mesotrione residues decrease with increasing PHIs.

Analysis of untreated control samples demonstrated that they were less then the LOQ (0.01 ppm).

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable for okra.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP#: 338109].

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The following deviations from regulatory requirements were reported: (1) Weather data were not collected according to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)-GLP requirements; National Oceanic and Atmospheric Administration (NOAA) weather data were reported; (2) Tank mix storage stability data were not generated as required in 40 CFR 160.113(a)(3); (3) Maintenance chemicals and irrigation were not applied under GLP; (4) Soil characterization analysis was not conducted under GLP. These deviations did not impact the validity of the study.

A. BACKGROUND INFORMATION

Mesotrione is a triketone herbicide which inhibits the enzyme *p*-hydroxyphenylpyruvate dioxygenase (HPPD), disrupting carotenoid biosynthesis. This process leads to the destruction of chlorophyll, resulting in a bleaching effect in susceptible plants. Mesotrione is intended for preemergence and postemergence use for selective control of annual broadleaf weeds in field, pop, and sweet corn. The nomenclature of mesotrione is summarized in Table A.1, and the physicochemical properties of mesotrione are summarized in Table A.2.

TABLE A.1. Mesotrione Nomenclature.

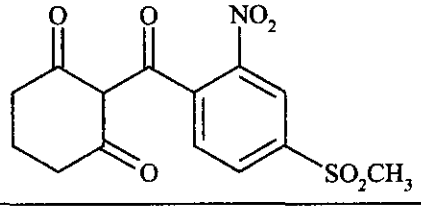
Chemical structure	
Common name	Mesotrione
Company experimental name	ZA01296
IUPAC name	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
CAS name	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
CAS registry number	104206-82-8
End-use product (EP)	Callisto® 4SC

TABLE A.2. Physicochemical Properties of Mesotrione.

Parameter	Value	Reference
Melting range	148.7-152.5°C	RD Memo, H. Podall, 24-FEB-2000; DP#: 263245.
pH	3.4 (1% dispersion in water; 25°C)	
Density	1.46 g/mL, 20°C	
Water solubility	20°C 160 ppm, unbuffered water 0.22 g/100 mL, pH 4.8 1.5 g/100mL, pH 6.9 2.2 g/100 mL, pH 9	
Solvent solubility	20°C 0.37 g/100 mL, methanol 1.7 g/100 mL, ethyl acetate 0.27 g/100 mL, toluene 10.4 g/100 mL, acetonitrile <0.03 g/100 mL, heptane 8.1 g/100 mL, acetone	
Vapor pressure	4.3×10^{-8} torr, 20°C	
Dissociation constant, pK_a	3.12, 20°C	
Octanol/water partition coefficient, Log(K_{OW})	20°C log P_{OW} = 0.11 in unbuffered water log P_{OW} = 0.90 in pH 5 buffer log P_{OW} <-1 at pH 7 and 9 buffered water	
UV/visible absorption spectrum	Absorption maximum in methanol at 256 mu, with a molar extinction coefficient of 2.24×10^4 M cm.	

B. EXPERIMENTAL DESIGN

Okra was grown under normal agricultural conditions in trial plots at each of the field trials. The control plots were separated sufficiently to exclude any contamination from the treated plots.

Okra plants at all five trial sites were treated with Callisto® 4SC, a formulation of mesotrione, using one of the five following treatment regimes: (1) PSS spray at a rate of 0.196-0.205 lbs ai/A (0.22-0.23 kg ai/ha); (2) PSS spray followed by a POT spray for a total rate of 0.285-0.301 lbs ai/A (0.32-0.38 kg ai/ha); (3) PSS spray followed by a PD application for a total rate of 0.293-0.300 lbs ai/A (0.33-0.34 kg ai/ha); (4) POT spray at 0.093-0.097 lbs ai/A (0.105-0.109 kg ai/ha); and (5) PD application at 0.086-0.096 lbs ai/A (0.097-0.107 kg ai/ha). Applications were made using ground equipment and backpack sprayers at a total treatment regime volume of 4-50 GPA (37-466 L/ha). An adjuvant (0.25% (v:v) NIS) was added to the spray mixture for application regimes 2 through 5.

For each of the field trials, one untreated and two treated mature okra RAC samples were harvested by hand after each of the various spraying regimes. For treatment regimes including POT treatment, samples were collected 45 days after application (45 day PHI). For treatment PHIs were considered not applicable for those treated by PSS only. Samples were collected from the control plot first and then from the treated plot, avoiding the plot boundaries and row ends. For trial 3A-HR-05-6262, some POT spray samples were collected at a PHI of 52 days instead of 45 days. Additionally, at the Texas site (SA-HR-05-6263), one control sample and duplicate treated samples were harvested at 0, 15, 30, 45 and 52 days after treatment for samples incorporating treatment by POT spray, and 0, 14, 21, 28, and 35 days after treatment for samples incorporating treatment by PD application to determine residue decline.

Approximately 2.5 lbs of mature okra pods were collected from at least 12 separate plants from at least 2 levels on the plant. Duplicate samples were taken from each of the treated plots. The sample weight for decline was at least 50% less than the above weight. At trial site VQ-HR-05-6261, plants at most of the plots were severely injured and samples could not be taken, samples could only be collected from 2 of the 10 plots. Insufficient sample weights (<2.5 pounds) were collected in several of the plots at Trial Site 3A-HR-05-6262.

After collection, okra pod samples were stored frozen, and then shipped frozen to Syngenta's Greensboro, NC facility via Agricultural Chemicals Development Service (ACDS).

Cultivation and trial maintenance methods were conducted in accordance with local agricultural practices; maintenance chemicals used at each trial site during the study were reported. Average monthly minimum and maximum temperatures, and total monthly precipitation amounts were reported for each trial from planting to harvest. According to the Study Report, temperature and precipitation were generally typical at each site as compared to historical 10-year data. The historical data were only reported for precipitation. No unusual weather conditions occurred during the study except for more than normal rainfall overall at three sites: SJ-HR-05-6260, VQ-HR-05-6261, 3A-HR-05-6262 and less than normal rainfall at one site: SA-HR-05-6263. Four sites were supplemented with irrigation.

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State, EPA Region; Year (Trial No.)	Soil characteristics[1]					
	Type	% OM	pH	CEC (meq/g)	Overall Monthly Rainfall Range (inches)	Overall Monthly Temperature Range (°F)
Seven Springs, NC, Region 2; 2005 (SJ-HR-05-6260)	Sandy Loam	0.9	5.8	5.1	2.9–11.1	23-102
Vero Beach, FL, Region 3; 2005 (VQ-HR-05-6261)	Sand	0.5	7.4	5.1	3.4-13.8	58-97
Leland, MS, Region 4; 2005 (3A-HR-05-6262)	Silt Loam	0.6	7.2	6.6	4.2-7.0	52-103
East Bernard, TX, Region 6; 2005 (SA-HR-05-6263)	Clay	1.1	7.5	14.2	0.2-5.9	50-106
Comanche, OK, Region 6; 2005 (SC-HR-05-6264)	Sandy Clay Loam	1.3	6.7	14.8	1.6-5.8	N/A

[1] OM = organic matter; CEC = cation-exchange capacity.

TABLE B.1.2. Study Use Pattern.

Location City, State, Region; Year (Trial ID)	EP[1]	Application						
		Application Method/ Timing	Growth Stage	Volume[2] GPA [L/ha]	Rate (lb ai/A) [g ai/ha]	RTI[3] (days)	Total Rate (lb ai/A) [g ai/ha]	Tank Mix Adjuvants
Seven Springs, NC, Region 2; 2005 (SJ-HR-05-6260)	Callisto 4.0 SC	1. PSS	00	3.98 [37]	0.201 [225]	NA	0.201 [225]	NA
		2. PSS + POT	00 + 2-3 leaf	8.03 [75]	0.204 + 0.094 [229 + 105]	28	0.298 [334]	NIS 0.25%
		3. PSS + PD	00 + (36) 9 leaf	24.6 [230]	0.203 + 0.094 [228 + 105]	45	0.297 [333]	NIS 0.25%
		4. POT	2-3 leaf	4.02 [37.6]	0.095 [106]	NA	0.095 [106]	NIS 0.25%
		5. PD	(38) 10 leaf	20.6 [192]	0.094 [105]	NA	0.094 [105]	NIS 0.25%
Vero Beach, FL, Region 3; 2005 (VQ-HR-05-6261)	Callisto 4.0 SC	1. PSS	00	25.0 [234]	0.200 [224]	NA	0.200 [224]	NA
		2. PSS + POT	00 + 12-13 leaf	49.8 [466]	0.200 + 0.094 [224 + 105]	25	0.294 [329]	NIS 0.25%
		3. PSS + PD	00 + 69 leaf	48.3 [451]	0.200 + 0.094 [224 + 106]	42	0.294 [330]	NIS 0.25%
		4. POT	12-13 leaf	24.8 [232]	0.093 [105]	NA	0.093 [105]	NIS 0.25%
		5. PD	69 leaf	21.3 [199]	0.086 [97]	NA	0.086 [97]	NIS 0.25%
Leland, MS, Region 4; 2005 (3A-HR-05-6262)	Callisto 4.0 SC	1. PSS	00	16.3 [152]	0.205 [229]	NA	0.205 [229]	NA
		2. PSS + POT	00 + 13	31.8 [297]	0.207 + 0.094 [232 + 105]	18	0.301 [337]	NIS 0.25%
		3. PSS + PD	00 + Pre-bloom	35.7 [334]	0.208 + 0.092 [233 + 103]	41	0.300 [336]	NIS 0.25%
		4. POT	13	15.8 [148]	0.097 [109]	NA	0.097 [109]	NIS 0.25%
		5. PD	Pre-bloom	19.8 [185]	0.095 [106]	NA	0.095 [106]	NIS 0.25%
East Bernard, TX, Region 6; 2005	Callisto 4.0 SC	1. PSS	00	14.9 [140]	0.203 [228]	NA	0.203 [228]	NA

TABLE B.1.2. Study Use Pattern.

Location City, State, Region; Year (Trial ID)	EP[1]	Application						
		Application Method/ Timing	Growth Stage	Volume[2] GPA [L/ha]	Rate (lb ai/A) [g ai/ha]	RTI[3] (days)	Total Rate (lb ai/A) [g ai/ha]	Tank Mix Adjuvants
East Bernard, TX, Region 6; 2005 (SA-HR-05-6263)	Callisto 4.0 SC	2. PSS + POT	00 + 89	30.4 [284]	0.204 + 0.093 [228 + 105]	67	0.297 [333]	NIS 0.25%
		3. PSS + PD	00 + 89	29.7 [278]	0.199 + 0.094 [223 + 106]	84	0.294 [329]	NIS 0.25%
		4. POT	89	15.9 [148]	0.096 [108]	NA	0.096 [108]	NIS 0.25%
		5. PD	89	15.3 [143]	0.096 [107]	NA	0.096 [107]	NIS 0.25%
Comanche, OK, Region 6; 2005 (SC-HR-05-6264)	Callisto 4.0 SC	1. PSS	00	12.0 [112]	0.196 [220]	NA	0.196 [220]	NA
		2. PSS + POT	00 + 13	23.6 [221]	0.191 + 0.093 [214 + 105]	30	0.285 [319]	NIS 0.25%
		3. PSS + PD	00 + 59	24.3 [227]	0.120 + 0.093 [224 + 104]	47	0.293 [328]	NIS 0.25%
		4. POT	13	11.9 [112]	0.094 [105]	NA	0.094 [105]	NIS 0.25%
		5. PD	53	12.4 [116]	0.095 [107]	NA	0.095 [107]	NIS 0.25%

[1] EP = End-use Product; Callisto ® 4SC Herbicide (EPA Reg. No. 100-1131).
[2] GPA = gallons per acre.
[3] Retreatment Interval.
PSS = Preemergence soil-surface spray application, POT = Post-emergence over-the-top application, PD = Post-emergence direct application.
NA = Not Applicable.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Regions	Okra		
	Submitted	Requested	
		Canada	U.S.
2	1		1
3	1		1
4	1		1
6	2		2
Total	5		5

B.2. Sample Handling and Preparation

After collection, okra pod samples were stored frozen at the field site. Samples remained frozen at the field site until shipment to Syngenta, Greensboro, NC via ACDS freezer truck or overnight courier with dry ice. Samples were kept under frozen conditions at the laboratory (<-15°C) until further preparation, extraction, and analysis. Okra samples were cut into approximately two-inch pieces with a meat cleaver or hand shearers, then composited and ground in a food cutter. Dry ice was used, as necessary, to keep the sample frozen. After preparation, samples were place in labeled double polyethylene bags and store frozen at <-15°C until analyzed.

B.3. Analytical Methodology

Okra samples were analyzed for residues of mesotrione using Method RAM 366/01 (LC-MS/MS) with modifications as follows. A 10-gram sub-sample was Polytron-homogenized for 3-5 minutes with 100 mL of 50% ACN/H_2O (acetonitrile/water) after addition of one gram of sodium chloride (NaCl). Approximately 40 mL of the mixture was centrifuged and an aliquot was taken from the supernatant and diluted with water. The final volume was adjusted with 90% H_2O/methanol (MeOH). The sample final solution was injected onto a LC-MS/MS system for residue analysis. The LOQ was 0.01 ppm for mesotrione for okra.

C. RESULTS AND DISCUSSION

Sample storage conditions and intervals are summarized in Table C.2. The maximum storage interval of okra samples, from harvest to extraction, was 409 days (13 months). Samples were stored frozen at the field sites for 6-145 days; however temperatures at field sites were not provided. Samples were shipped frozen from the field site to the laboratory, taking anywhere from 0-39 days from date of shipment to date of receipt. Again, temperatures during transit were not reported. At the analytical laboratory, samples were stored frozen at a temperature of <-15°C. Storage stability data indicate mesotrione is stable in okra for up to 13 months (refer to 47013801.der). Based on these results, residues of mesotrione are expected to be stable in okra over the storage interval of this study. Field sample residues were not corrected for in-storage dissipation.

Okra samples were analyzed for residues of mesotrione using Method RAM 366/01 (LC-MS/MS) with modifications. The samples were analyzed within 1 to 12 days of extraction. The validated LOQ was 0.01 ppm for mesotrione in okra. Method validation results, apart from concurrent recoveries, were not provided for the method used in this study. Concurrent method recoveries are reported in Table C.1. Concurrent recoveries from controls fortified with mesotrione at 0.01 to 10 ppm ranged from 70% to 111% (average of 88% with a standard deviation of 11%, n=26). The average recoveries for mesotrione were in the generally accepted range of 70% to 120%. The fortification levels encompassed the expected residues in okra. The method was adequate for data collection based on acceptable concurrent method recoveries.

Residue data from the okra field trials are reported in Table C.3. A summary of the residue data for okra is presented in Table C.4. Residues of mesotrione harvested after PSS spray only were less than the LOQ (0.01 ppm) in all samples. Residues of mesotrione harvested 45 days after the final treatment for the PSS+POT treatment regime and the POT only treatment regime were less than the LOQ (0.01 ppm) in all samples. Residues of mesotrione harvested 28 days after the final treatment for the PSS+PD treatment regime and the PD only treatment regime were less than the LOQ (0.01 ppm) in all samples.

In the decline trial, all residues in the okra samples were <0.01, except for the samples harvested at day 0 for the PSS+POT treatment regime (0.09 ppm and 0.2 ppm) and the POT only treatment regime (0.19 ppm and 0.16 ppm). Residues of mesotrione were non-quantifiable (<0.01 ppm) in/on all untreated okra samples.

TABLE C.1. Summary of Concurrent Recoveries of Mesotrione from Okra.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev (%)	Overall Mean ± std dev (%)
Mesotrione (ZA 01296)					
Okra	0.01	13	69.9, 70.5, 71.5, 73.2, 75.9, 78.2, 79.4, 79.7, 83.6, 83.7, 84.4, 87.9, 100.5	79.9 ± 8.5	87.6 ± 11.4
	0.1	7	85.4, 86.5, 88.4, 88.9, 91.9, 95.4, 100.7	91.0 ± 5.4	
	1.0	6	90.3, 92.2, 98.3, 99.1, 110.1, 111.4	100.2 ± 8.8	

TABLE C.2. Summary of Storage Conditions.

Matrix (RAC)	Analyte	Storage Temperature (°C)	Actual Storage Duration (month)	Interval of Demonstrated Storage Stability* (months)
Okra	Mesotrione	<-15°C	11-13	13

* Storage stability demonstrated in/on okra (refer to 47013801.der).

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial No.)	Okra Variety	Commodity	Application Method	Total Rate (lb ai/A) [g ai/ha]	PHI (days)	Uncorrected Mesotrione Residue (ppm)
Seven Springs, NC, Region 2; 2005 (SJ-HR-05-6260)	Clemson Spineless	Pods	PSS	0.201 [225]	NA	<0.01, <0.01
			PSS + POT	0.298 [334]	45	<0.01, <0.01
			PSS + PD	0.297 [333]	28	<0.01, <0.01
			POT	0.095 [106]	45	<0.01, <0.01
			PD	0.094 [105]	28	<0.01, <0.01
Vero Beach, FL, Region 3; 2005 (VQ-HR-05-6261)	Clemson Spineless 80	Pods	PSS	0.200 [224]	NA	NS, NS
			PSS + POT	0.294 [329]	45	NS, NS
			PSS + PD	0.294 [330]	28	NS, NS
			POT	0.093 [105]	45	<0.01, <0.01
			PD	0.086 [97]	28	NS, NS
Leland, MS, Region 4; 2005 (3A-HR-05-6262)	Perkins Long	Pods	PSS	0.205 [229]	NA	NS, NS
			PSS + POT	0.301 [337]	45	<0.01, <0.01
			PSS + PD	0.300 [336]	28	<0.01, <0.01
			POT	0.097 [109]	45	<0.01, <0.01
			PD	0.095 [106]	28	<0.01, <0.01
East Bernard, TX,	Louisiana	Pods	PSS*	0.203	0	<0.01, <0.01

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial No.)	Okra Variety	Commodity	Application Method	Total Rate (lb ai/A) [g ai/ha]	PHI (days)	Uncorrected Mesotrione Residue (ppm)
Region 6; 2005 (SA-HR-05-6263)	Green Velvet			[228]	14	<0.01, <0.01
					21	<0.01, <0.01
					28	<0.01, <0.01
					35	<0.01, <0.01
			PSS + POT	0.297 [333]	0	0.09, 0.2
					15	<0.01, <0.01
					30	<0.01, <0.01
					45	<0.01, <0.01
					52	<0.01, <0.01
			PSS + PD	0.294 [329]	0	<0.01, <0.01
					14	<0.01, <0.01
					21	<0.01, <0.01
					28	<0.01, <0.01
					35	<0.01, <0.01
East Bernard, TX, Region 6; 2005 (SA-HR-05-6263)	Louisiana Green Velvet	Pods	POT	0.096 [108]	0	0.19, 0.16
					15	<0.01, <0.01
					30	<0.01, <0.01
					45	<0.01, <0.01
					52	<0.01, <0.01
			PD	0.096 [107]	0	<0.01, <0.01
					14	<0.01, <0.01
					21	<0.01, <0.01
					28	<0.01, <0.01
					35	<0.01, <0.01
Comanche, OK, Region 6; 2005 (SC-HR-05-6264)	Clemson Spineless	Pods	PSS	0.196 [220]	NA	<0.01, <0.01
			PSS + POT	0.285 [319]	45	<0.01, <0.01
			PSS + PD	0.293 [328]	28	<0.01, <0.01
			POT	0.094 [105]	45	<0.01, <0.01
			PD	0.095 [107]	28	<0.01, <0.01

* Days reported under PHI correspond to the difference in the day of harvest and the day of the last application for PSS+PD, as reported by the study author.
LOQ = 0.01 ppm for mesotrione. NA = Not Applicable for this spray regime, NS = No Sample, insufficient sample for harvest.

TABLE C.4. Summary of Residue Data from Crop Field Trials with Mesotrione.

Matrix	Total Application Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels[1] (ppm)						
			n	Min.	Max.	HAFT[2]	Median	Mean	SD
Mesotrione (PSS)									
Okra	0.196-0.205 [0.22-0.23]	NA	10	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Mesotrione (PSS + POT)									
Okra	0.285-0.301 [0.32-0.38]	45	10	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Mesotrione (PSS + PD)									
Okra	0.293-0.300 [0.33-0.34]	28	10	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Mesotrione (POT)									
Okra	0.093-0.097 [0.105-0.109]	45	10	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Mesotrione (PD)									
Okra	0.086-0.096 [0.097-0.107]	28	10	<0.01	<0.01	<0.01	<0.01	<0.01	NA

[1] LOQ = 0.01 ppm for mesotrione.
[2] HAFT = Highest-Average Field Trial.

D. CONCLUSION

The submitted field trial data are adequate and reflect the use of five different regimes of spray applications of the Callisto® SC formulation of mesotrione at total rates of 0.086 to 0.301 lb ai/A on okra grown in the U.S. with a 28 or 45-day PHI. An acceptable method was used for quantitation of residues in/on okra based on untreated control sample spike recoveries.

Okra sample storage intervals between sampling, extraction and analysis ranged from 11 to 13 months. Mesotrione residues were found to be stable in okra under freezer storage conditions for at least 13 months (refer to 47013801.der). Based on these results, residues of mesotrione are expected to be stable in okra over the storage interval of this study.

Residues of mesotrione in okra harvested after PSS spray only were less than the LOQ (0.01 ppm) in all samples. Residues of mesotrione in okra harvested 45 days after the final treatment for the PSS+POT treatment regime and the POT only treatment regime were less than the LOQ (0.01 ppm) in all samples. Residues of mesotrione in okra harvested 28 days after the final treatment for the PSS+PD treatment regime and the PD only treatment regime were less than the LOQ (0.01 ppm) in all samples.

In the decline trial, all residues in the okra samples were <0.01 ppm, except for the samples harvested at day 0 for the PSS+POT treatment regime (0.09 ppm and 0.2 ppm) and the POT only treatment regime (0.19 ppm and 0.16 ppm). Residue decline data show that mesotrione residues decrease with increasing PHIs. Analysis of untreated control samples demonstrated that they were less then the LOQ (0.01 ppm).

E. REFERENCES

DP#s: 245477 and 260267
Subject: PP#: 8F04954. Mesotrione in/on Field Corn. Evaluation of Residue Data and Analytical Methods. PC Code: 122990. DP Barcodes: D245477, and D260267. Case #: 289589. Submission #s: S541377, and S569871. MRID #s: 44505118, 44505212-23, 44537109-12, 44901719, and 44942401-03.
From: Sarah Levy
To: Jim Stone/Jim Tompkins
Date: 06-JUN-2001
MRID#: 47136802

DP#: 283827
Subject: Mesotrione. Summary of Analytical Chemistry and Residue Data for Sweet Corn, PP#2F06443, and Response to Data Deficiencies of a Previous HED Review (PP#8F04954, DP Barcodes: D245477 and D260267, 6/6/01, S. Levy).
From: William Cutchin
To: J. Stone/J. Miller
Date: 12-JAN-2005
MRID#: 45651803

DP#: 263245
Subject: Product Chemistry Review of Mesotrione (ZA 1296 Technical (dry)).
From: H. Podall
To: J. Tompkins/J. Stone
Date: 24-FEB-2000
MRID#s: 44373503-44373505, 44505003, 44505004, and 44901701

F. DOCUMENT TRACKING

RDI: G.F. Kramer (05-DEC-2007), RAB1 Chemists (03-OCT-2007)
S. Levy:S10953:PY1:(703)305-0783:7509P:RAB1
Petition #: 6F7162
DP#: 338109
PC Code: 122990

Template Version June 2005

Mesotrione/ZA01296/Syngenta Crop Protection, Inc.
DACO 7.4.1/7.4.2/OPPTS 860.1500&1520/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial/ Residue Decline/Processing Study – Sugarcane

Primary Evaluator: Sarah J. Levy, Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509P)
Date: 05-DEC-2007

Approved by: George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)
Date: 05-DEC-2007

Note: This data-evaluation record (DER) was originally prepared by Tetrahedron, Inc, subcontractor for Versar, Inc. (6850 Versar Center, Springfield, VA 22151; submitted 31-MAY-2007). The DER has been reviewed by the HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORTS:

MRID#: 47013805. Lin, K. (2006). Mesotrione - Magnitude of the Residues in or on Sugarcane. Lab Project Number: T020420-04, Task Number: T020420-04. Unpublished study prepared by Syngenta Crop Protection, Inc. 143 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted field trial data for mesotrione in/on sugarcane. Eight field trials (six harvest and two decline) were conducted in the U.S. encompassing Regions 3 (3 trials in FL), 4 (3 trials in LA), 6 (1 trial in TX), and 13 (1 trial in HI) during the 2005 growing season. At each trial location, there was one untreated and five treated plots.

The treated plots were treated with Callisto® 4SC, a 4 lb/gal soluble-concentrate (SC) formulation of mesotrione, using one of the following three treatment regimes: (1) preemergence soil-surface (PSS) spray followed by a post-emergence over-the-top (POT) broadcasting spray for a total rate of 0.318-0.360 lb ai/A (0.372-0.403 kg ai/ha); (2) PSS spray followed by a post-direct (PD) application for a total of 0.325-0.348 lb ai/A (0.364-0.389 kg ai/ha); and, (3) POT broadcasting spray followed by a PD application for a total of 0.184-0.202 lb ai/A (0.206-0.226 kg ai/ha). Additionally, sugarcane was treated at exaggerated rates by one-time POT spray followed by one-time PD spray at two field trial sites (VN-HR-05-6241 and SD-HR-05-6244), for a processing study. Total treatment regime volumes ranged from 4-51 gallons/acre (GPA) (39-476 L/ha). An adjuvant (crop-oil concentrate (COC)) was added to the tank mixtures for POT and PD applications.

For each of the field trials, one untreated and two treated mature sugarcane raw agricultural commodity (RAC) samples were collected after each of the various spraying regimes. Sugarcane samples were harvested at 114 days after the last application for PSS+POT treatment [114 days pre-harvest interval (PHI)] and 100 days after the last application for PSS+PD and POT+PD treatments (100 days PHI). In the decline trials (VN-HR-05-6240 and SD-HR-05-6243), sugarcane samples were collected at 0, 30, 60, 114 and 121 days for samples treated by PSS+POT, and 0, 30, 60, 100, and 107 days for samples treated by PSS+PD or POT+PD.

Sugarcane samples were analyzed for residues of mesotrione using Method RAM 366/01 (liquid chromatography with tandem mass-spectrometry detectors (LC-MS/MS)) with modifications. This method was previously reviewed and forwarded to the U.S. Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual (PAM) Volume II as a confirmatory enforcement method for plant commodities (Memo, W. Cutchin, 12-JAN-2005; DP#: 283827). The method was adequate for data collection based on acceptable concurrent method recoveries.

Sugarcane samples were stored frozen prior to analysis; the maximum storage interval from harvest to extraction was 13 months. Sample storage intervals between sampling, extraction and analysis ranged from 7 to 13 months. Mesotrione residues were found to be stable in sugarcane under freezer storage conditions for at least 13 months (refer to 47013801.der). Based on these results, residues of mesotrione are expected to be stable in sugarcane over the storage interval of this study.

Residues of mesotrione in sugarcane harvested at 114 days after treatment (PSS+POT) and 100 days after treatment (PSS+PD and POT+PD) were less than the limit of quantitation (LOQ = 0.01 ppm) in all samples.

For the two decline trials, residues of mesotrione ranged from <0.01 to 5.75 ppm. The only measurable residues occurred for samples harvested at day 0. Decline data show mesotrione residues decrease with increasing PHIs.

Residues of mesotrione in sugarcane harvested at 100 days after being treated at exaggerated application rates (POT+PD) were less than the LOQ (0.01 ppm) in all samples. Additional samples were collected for analysis of sugarcane processed fractions (refined sugar and molasses), but were not analyzed. Residues of mesotrione were <LOQ (<0.01 ppm) in/on all untreated sugarcane samples.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial and processing residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP#: 338109].

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The following deviations from regulatory requirements were reported: (1) Weather data were not collected according to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)-GLP requirements; National Oceanic and Atmospheric Administration (NOAA) weather data were reported; (2) Tank mix storage stability data were not generated as required in 40 CFR 160.113(a)(3); (3) Maintenance chemicals and irrigation were not applied under GLP; and, (4) Soil characterization analysis was not conducted under GLP. These deviations did not impact the validity of the study.

A. BACKGROUND INFORMATION

Mesotrione is a triketone herbicide which inhibits the enzyme *p*-hydroxyphenylpyruvate dioxygenase (HPPD), disrupting carotenoid biosynthesis. This process leads to the destruction of chlorophyll, resulting in a bleaching effect in susceptible plants. Mesotrione is intended for preemergence and postemergence use for selective control of annual broadleaf weeds in field, pop, and sweet corn. The nomenclature of mesotrione is summarized in Table A.1, and the physicochemical properties of mesotrione are summarized in Table A.2.

TABLE A.1. Mesotrione Nomenclature.

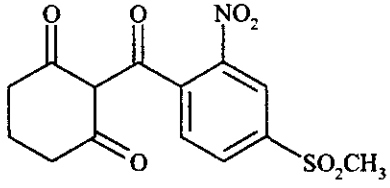
Chemical structure	
Common name	Mesotrione
Company experimental name	ZA01296
IUPAC name	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
CAS name	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
CAS registry number	104206-82-8
End-use product (EP)	Callisto® 4SC

TABLE A.2. Physicochemical Properties of Mesotrione.

Parameter	Value	Reference
Melting range	148.7-152.5°C	RD Memo, H. Podall, 24-FEB-2000; DP#: 263245.
pH	3.4 (1% dispersion in water; 25°C)	
Density	1.46 g/mL, 20°C	
Water solubility	20°C 160 ppm, unbuffered water 0.22 g/100 mL, pH 4.8 1.5 g/100mL, pH 6.9 2.2 g/100 mL, pH 9	
Solvent solubility	20°C 0.37 g/100 mL, methanol 1.7 g/100 mL, ethyl acetate 0.27 g/100 mL, toluene 10.4 g/100 mL, acetonitrile <0.03 g/100 mL, heptane 8.1 g/100 mL, acetone	
Vapor pressure	4.3×10^{-8} torr, 20°C	
Dissociation constant, pK_a	3.12, 20°C	
Octanol/water partition coefficient, Log(K_{OW})	20°C log P_{OW} = 0.11 in unbuffered water log P_{OW} = 0.90 in pH 5 buffer log P_{OW} <-1 at pH 7 and 9 buffered water	
UV/visible absorption spectrum	Absorption maximum in methanol at 256 mu, with a molar extinction coefficient of 2.24×10^4 M cm.	

B. EXPERIMENTAL DESIGN

Sugarcane was grown under normal agricultural conditions in trial plots at each of the field trials. The control plots were separated sufficiently to exclude any contamination from the treated plots.

The treated plots were treated with Callisto® 4SC, a formulation of mesotrione, in three different treatment regimes: (1) by a PSS spray at a rate of 0.24 pounds ai/A (269 g ai/ha) followed by a POT broadcasting spray at 0.094 lbs ai/A (105 g ai/ha), for a total of 0.334 lb ai/A (374 g ai/ha); (2) by a PSS spray at a rate of 0.24 lbs ai/A followed by a PD application at 0.094 lbs ai/A, for a total of 0.334 lb ai/A; and, (3) by a POT broadcasting spray at 0.094 lbs ai/A followed by a PD application at 0.094 ai/A, for a total of 0.188 lb ai/A (211 g ai/ha). Additionally, sugarcane was treated at exaggerated rates by one-time POT spray followed by one-time PD spray at two field trial sites (VN-HR-05-6241 and SD-HR-05-6244). Applications were made using ground equipment and backpack sprayers at a total treatment regime volume of 4-51 GPA (39-476 L/ha). An adjuvant (e.g., spreader/sticker) was added to the tank mixes for the POT and PD applications.

For each of the field trials, one untreated and two treated mature sugarcane RAC samples were collected after each of the various spraying regimes. Sugarcane samples were harvested approximately 114 days after the last application for PSS+POT treatment [114 days PHI] and 100 days after the last application for PSS+PD and POT+PD treatments (100 days PHI). In the decline trials (VN-HR-05-6240 and SD-HR-05-6243), sugarcane samples were collected at 0, 30, 60, 114 and 121 days for samples treated by PSS+POT, and at 0, 30, 60, 100, and 107 days for samples treated by PSS+PD or POT+PD. Samples were collected from the control plot first and then from the treated plot, avoiding the plot boundaries and row ends.

After collection, sugarcane samples were stored frozen and then shipped frozen to Syngenta's Greensboro, NC facility via Agricultural Chemicals Development Service (ACDS).

Cultivation and trial maintenance methods were conducted in accordance with local agricultural practices; maintenance chemicals used at each trial site during the study were reported. Average monthly minimum and maximum temperatures, and total monthly precipitation amounts were reported for each trial from planting to harvest. According to the Study Report, temperature and precipitation were within historical averages. The historical data were only reported for precipitation. No unusual weather conditions occurred during the study except for more than normal rainfall overall at the three FL sites: VN-HR-05-6240, VN-HR-05-6241, VN-HR-05-6242 and less than normal rainfall at four sites: SD-HR-05-6243, SD-HR-05-6244, SD-HR-05-6245 and SA HR-05-6246. Two sites, SA HR-05-6246 and WD- HR-05-6247 used supplemental irrigation.

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State, EPA Region; Year (Trial No.)	Soil characteristics[1]				Meteorological Data	
	Type	%OM	pH	CEC meq/g	Overall Monthly Rainfall Range (inches)	Overall Monthly Temperature Range (°F)
South Bay, FL, Region 3; 2005 (VN-HR-05-6240)	Peat/muck	50.1	8.0	42.7	1.60–11.55	44-97
South Bay, FL, Region 3; 2005 (VN-HR-05-6241)	Peat/muck	50.1	8.0	42.7	1.60–11.55	44-97
South Bay, FL, Region 3; 2005 (VN-HR-05-6242)	Peat/muck	50.1	8.0	42.7	1.60–11.55	44-97
Bunkie, LA, Region 4; 2005 (SD-HR-05-6243)	Loam	1.1	5.8	5.7	0.46-4.35	31-103
Cheneyville, LA, Region 4; 2005 (SD-HR-05-6244)	Sandy Loam	0.9	6.6	5.5	1.64-4.35	32-103
Washington, LA, Region 4; 2005 (SD-HR-05-6245)	Clay	1.8	5.0	18.9	0.14-8.69	36-98
Raymondville, TX, Region 6; 2005 (SD-HR-05-6246)	Clay Loam	1.3	8.1	20.4	0.15-3.77	35-102
Puunene, HI, Region 13; 2005 (WD-HR-05-6247)	Sandy Loam	3.6	7.8	27.7	0.05-4.24	51-94

[1] OM = organic matter; CEC = cation-exchange capacity.

TABLE B.1.2. *Study Use Pattern.*

Trial Identification: (County, Nearest City, State, EPA Region, Year) (Trial No.)	EP[1]	Application Method/ Timing[2]	Volume[3] (GPA) [L/ha]	Rate (lb ai/A) [g ai/ha]	RTI[4] (days)	Total Rate (lb ai/A) [g ai/ha]	Tank Mix Adjuvants
South Bay, FL, Region 3: 2005 (VN-HR-05-6240)	Callisto 4.0 SC	1. PSS + POT	50.6 [473]	0.242 + 0.094 [271 + 106]	156	0.336 [376]	POT + 1% COC
		2. PSS + PD	50.3 [470]	0.241 + 0.095 [270 + 106]	170	0.336 [376]	PD + 1% COC
		3. POT + PD	50.4 [471]	0.093 + 0.095 [104 + 106]	14	0.188 [210]	POT + 1% COC PD + 1% COC
South Bay, FL, Region 3: 2005 (VN-HR-05-6241)	Callisto 4.0 SC	1. PSS + POT	50.1 [468]	0.240 + 0.093 [269 + 104]	156	0.332 [372]	POT + 1% COC
		2. PSS + PD	49.7 [465]	0.239 + 0.093 [268 + 104]	170	0.333 [373]	PD + 1% COC
		3. POT + PD	50.9 [476]	0.094 + 0.095 [105 + 106]	14	0.189 [212]	POT + 1% COC PD + 1% COC
		3. POT + PD	50.8 [475]	0.281 + 0.286 [315 + 320]	14	0.567 [635]	POT + 1% COC PD + 1% COC
		3. POT + PD	50.2 [469]	0.467 + 0.465 [523 + 521]	14	0.932 [1,044]	POT + 1% COC PD + 1% COC
South Bay, FL, Region 3: 2005 (VN-HR-05-6242)	Callisto 4.0 SC	1. PSS + POT	50.8 [475]	0.246 + 0.093 [275 + 104]	156	0.339 [380]	POT + 1% COC
		2. PSS + PD	50.5 [472]	0.241 + 0.096 [270 + 107]	170	0.336 [377]	PD + 1% COC
		3. POT + PD	50.3 [471]	0.095 + 0.093 [106 + 104]	14	0.188 [210]	POT + 1% COC PD + 1% COC
Bunkie, LA, Region 4: 2005 (SD-HR-05-6243)	Callisto 4.0 SC	1. PSS + POT	35.3 [330]	0.226 + 0.092 [253 + 103]	72	0.318 [356]	POT + 1% COC
		2. PSS + PD	26.6 [249]	0.233 + 0.092 [261 + 102]	86	0.325 [364]	PD + 1% COC

TABLE B.1.2. Study Use Pattern.

Trial Identification: (County, Nearest City, State, EPA Region, Year) (Trial No.)	EP[1]	Application Method/ Timing[2]	Volume[3] (GPA) [L/ha]	Rate (lb ai/A) [g ai/ha]	RTI[4] (days)	Total Rate (lb ai/A) [g ai/ha]	Tank Mix Adjuvants
		3. POT + PD	33.7 [315]	0.095 + 0.089 [107 + 100]	14	0.184 [206]	POT + 1% COC PD + 1% COC
Cheneyville, LA, Region 4: 2005 (SD-HR-05-6244)	Callisto 4.0 SC	1. PSS + POT	38.6 [361]	0.260 + 0.099 [292 + 111]	74	0.360 [403]	POT + 1% COC
		2. PSS + PD	26.5 [248]	0.246 + 0.092 [275 + 103]	88	0.338 [378]	PD + 1% COC
		3. POT + PD	34.5 [322]	0.096 + 0.106 [108+ 119]	14	0.202 [226]	POT + 1% COC PD + 1% COC
		3. POT + PD	34.0 [318]	0.293 + 0.296 [328 + 332]	14	0.589 [659]	POT + 1% COC PD + 1% COC
		3. POT + PD	33.5 [313]	0.504 + 0.481 [564 + 539]	14	0.985 [1,103]	POT + 1% COC PD + 1% COC
Washington, LA, Region 4: 2005 (SD-HR-05-6245)	Callisto 4.0 SC	1. PSS + POT	4.2 [39]	0.239 + 0.095 [267 + 106]	99	0.334 [374]	POT + 1% COC
		2. PSS + PD	13.8 [129]	0.239 + 0.094 [267 + 106]	113	0.333 [373]	PD + 1% COC
		3. POT + PD	14.0 [131]	0.095 + 0.095 [106 + 106]	14	0.190 [212]	POT + 1% COC PD + 1% COC
Raymondville, TX, Region 6: 2005 (SD-HR-05-6246)	Callisto 4.0 SC	1. PSS + POT	41.8 [391]	0.250 + 0.099 [280 + 110]	162	0.349 [391]	POT + 1% COC
		2. PSS + PD	41.4 [387]	0.252 + 0.096 [282 + 107]	162	0.348 [389]	PD + 1% COC
		3. POT + PD	41.2 [385]	0.099 + 0.094 [111 + 106]	14	0.194 [217]	POT + 1% COC PD + 1% COC
Puunene, HI, Region 13: 2005 (WD-HR-05-6247)	Callisto 4.0 SC	1. PSS + POT	47.0 [440]	0.239 + 0.094 [268 + 106]	82	0.334 [374]	POT + 1% COC
		2. PSS + PD	46.9 [439]	0.239 + 0.094 [268 + 105]	79	0.333 [373]	PD + 1% COC
		3. POT + PD	47.1 [440]	0.094 + 0.094 [106 + 105]	14	0.188 [211]	POT + 1% COC PD + 1% COC

[1] EP = End-use Product; was formulated as a suspension concentrate containing mesotrione, active ingredient (4.0 lb ai/gal).
[2] PSS = Preemergence soil-surface spray application, POT = Post-emergence over-the-top application, PD = Post-emergence direct application.
[3] GPA = gallons per acre.
[4] Retreatment Interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Regions	Sugarcane		
	Submitted	Requested	
		Canada	U.S.
3	3		3
4	3		3
6	1		1
13	1		1
Total	8		8

B.2. Sample Handling and Preparation

Twelve canes were collected from 12 separate areas of the treated plot. Duplicate samples were taken from each of the treated plots. Approximately 150 lbs (~ 75 lbs from each of the replicates) of mature stripped cane samples were taken from Field Trials VN-HR-05-6241 and SD-HR-05-6244 for a processing study. After collection, samples were stored frozen at the field site until shipment to Syngenta, Greensboro, NC via ACDS freezer truck. Canes were cut into

approximately two-inch pieces with hand shears. The composited samples were ground in a foodcutter. Dry ice was used as necessary to keep the sample frozen. After preparation, the samples were placed in labeled, double polyethylene bags and kept in frozen at <-15°C until analyzed.

B.3. Analytical Methodology

Sugarcane samples were analyzed for residues of mesotrione using Method RAM 366/01 (LC-MS/MS) with modifications. The method was adequate for data collection based on acceptable concurrent method recoveries. The following modifications were noted: A 10-gram sub-sample was Polytron-homogenized for 3-5 minutes with 100 mL of 50% ACN/H_2O (acetonitrile/water) after addition of one gram of sodium chloride (NaCl). Approximately 40 mL of the mixture was centrifuged and an aliquot was taken from the supernatant and diluted with water. The final volume was adjusted with 90% H_2O/methanol (MeOH). The sample final solution was injected onto a LC-MS/MS system for residue analysis. The LOQ was 0.01 ppm for mesotrione for sugarcane.

C. RESULTS AND DISCUSSION

Sample storage conditions and intervals are summarized in Table C.2. The maximum storage interval of sugarcane samples, from harvest to extraction, was 390 days (13 months). Samples were stored frozen at the field sites for 0 – 58 days; however temperatures at field sites were not provided. Samples were shipped frozen from the field site to the laboratory, taking anywhere from 0-40 days from date of shipment to date of receipt. Again, temperatures during transit were not reported. At the analytical laboratory, samples were stored frozen at a temperature of <-15°C. Storage stability data indicate mesotrione is stable in sugarcane for up to 13 months (refer to 47013801.der). Based on these results, residues of mesotrione are expected to be stable in sugarcane for the storage interval used in this study. Field sample residues were not corrected for in-storage dissipation.

Sugarcane samples were analyzed for residues of mesotrione using Method RAM 366/01 (LC-MS/MS) with modifications. The samples were analyzed within 0 to 8 days of extraction. The validated LOQ was 0.01 ppm for each analyte in sugarcane. Method validation results, apart from concurrent recoveries, were not provided for the method used in this study. Concurrent method recoveries are reported in Table C.1. Concurrent recoveries from controls fortified with mesotrione at 0.01 to 10 ppm ranged from 66.1% to 90.4% (overall average of 74.6% with a standard deviation of 6.3%, n=34). The average recoveries for mesotrione were in the generally accepted range of 70 to 120%. The fortification levels encompassed the expected residues in sugarcane. The method was adequate for data collection based on acceptable concurrent method recoveries.

Residue data from the sugarcane field trials and the decline trials are reported in Table C.3. A summary of residue data for sugarcane for the respective PHIs with mesotrione is found in Table C.4. Residues of mesotrione in sugarcane harvested at 114 days after treatment (PSS+POT) and 100 days after treatment (PSS+PD and POT+PD) were <LOQ (0.01 ppm) in all samples.

For the two decline trials, residues of mesotrione ranged from <0.01 to 5.75 ppm. The only measurable residues occurred for samples harvested at day 0. Decline data show mesotrione residues decrease with increasing PHIs.

Residues of mesotrione in sugarcane harvested at 100 days after being treated at exaggerated application rates (POT+PD) were less than the LOQ (0.01 ppm) in all samples. Samples were collected for analysis of sugarcane processed fractions (refined sugar and molasses), but were not analyzed. Residues of mesotrione were non-quantifiable (<0.01 ppm) in/on all untreated sugarcane samples.

TABLE C.1. Summary of Concurrent Recoveries of Mesotrione from Sugarcane.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± SD* (%)	Overall Mean ± SD (%)
Mesotrione					
Sugarcane	0.01	17	66.1, 67.7, 68.1, 68.9, 69.5, 69.8, 70.2, 70.2, 70.3, 70.5, 70.5, 71.9, 72.1, 72.2, 72.5, 73.5, 84.1	71.1 ± 3.9	74.6 ± 6.3
	0.05	2	69.6, 71.4	70.5	
	0.1	10	70.2, 72.2, 73.5, 74.9, 75.1, 76.8, 78.9, 80.2, 80.4, 81.1	76.3 ± 3.8	
	0.2	2	76.5, 89.3	83.2	
	0.5	1	86.9	86.9	
	1.0	1	81.6	81.6	
	10.0	1	90.4	90.4	

* Standard deviations for mean values were not calculated where the number of individual values used to calculate the mean was less than three.

TABLE C.2. Summary of Storage Conditions.

Matrix (RAC)	Analyte	Storage Temperature (°C)	Actual Storage Duration (months)	Interval of Demonstrated Storage Stability* (months)
Sugarcane	Mesotrione	<-15°C (lab)	11-13	13

* Storage stability demonstrated in/on sugarcane. Refer to 47013801.der.

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial No.)	Sugarcane Variety	Commodity	Application Method	Total Rate (lb ai/A) [g ai/ha]	PHI (days)	Uncorrected Residue (ppm) Mesotrione
South Bay, FL; 2005 (VN-HR-05-6240)	CP-2143	Canes	PSS + POT	0.336 [376]	0	0.03, 0.02
					30	<0.01, <0.01
					60	<0.01, <0.01
					114	<0.01, <0.01
					121	<0.01, <0.01
			PSS + PD	0.336 [376]	0	0.02, <0.01
					30	<0.01, <0.01
					60	<0.01, <0.01
					100	<0.01, <0.01
					107	<0.01, <0.01
			POT + PD	0.188 [210]	0	0.02, 0.07
					30	<0.01, <0.01
					60	<0.01, <0.01
					100	<0.01, <0.01
					107	<0.01, <0.01
South Bay, FL;2005 (VN-HR-05-6241)	CP-2086	Canes	PSS + POT	0.332 [372]	114	<0.01, <0.01
			PSS + PD	0.333 [373]	100	<0.01, <0.01
			POT + PD	0.189 [212]	100	<0.01, <0.01
			POT + PD	0.567 [635]	100	NH, NH
			POT + PD	0.932 [1044]	100	<0.01, <0.01
South Bay, FL; 2005 (VN-HR-05-6242)	CP-2086	Canes	PSS + POT	0.339 [380]	114	<0.01, <0.01
			PSS + PD	0.336 [377]	100	<0.01, <0.01
			POT + PD	0.188 [210]	100	<0.01, <0.01
Bunkie, LA; 2005 (SD-HR-05-6243)	LCP-85-384	Canes	PSS + POT	0.318 [356]	0	3.72, 5.75
					30	<0.01, <0.01
					60	<0.01, <0.01
Bunkie, LA; 2005 (SD-HR-05-6243)	LCP-85-384	Canes	PSS + POT	0.318 [356]	114	<0.01, <0.01
					121	<0.01, <0.01
			PSS + PD	0.325 [364]	0	0.70, 0.31
					30	<0.01, <0.01
					60	<0.01, <0.01
					100	<0.01, <0.01
					107	<0.01, <0.01
			POT + PD	0.184 [206]	0	0.07, 0.20
					30	<0.01, <0.01
					60	<0.01, <0.01
					100	<0.01, <0.01
					107	<0.01, <0.01
Cheneyville, LA; 2005 (SD-HR-05-6244)	LCP-85-384 Kleentek	Canes	PSS + POT	0.360 [403]	114	<0.01, <0.01
			PSS + PD	0.338 [378]	100	<0.01, <0.01
			POT + PD	0.202 [226]]	100	<0.01, <0.01
			POT + PD	0.589 [659]	100	<0.01, <0.01
			POT + PD	0.985 [1103]	100	<0.01, <0.01
Washington, LA; 2005 (SD-HR-05-6245)	384	Canes	PSS + POT	0.334 [374]	114	<0.01, <0.01
			PSS + PD	0.333 [373]	100	<0.01, <0.01
			POT + PD	0.190 [212]	100	<0.01, <0.01
Raymondville, TX; 2005 (SD-HR-05-6246)	3388	Canes	PSS + POT	0.349 [391]	114	<0.01, <0.01
			PSS + PD	0.348 [389]	100	<0.01, <0.01
			POT + PD	0.194 [217]	100	<0.01, <0.01
Puunene, HI; 2005	65-7052	Canes	PSS + POT	0.334 [374]	114	<0.01, <0.01

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial No.)	Sugarcane Variety	Commodity	Application Method	Total Rate (lb ai/A) [g ai/ha]	PHI (days)	Uncorrected Residue (ppm) Mesotrione
(WD-HR-05-6247)			PSS + PD	0.333 [373]	100	<0.01, <0.01
			POT + PD	0.188 [211]	100	<0.01, <0.01

LOQ = 0.01 ppm for mesotrione. NH = Not Harvested; residues from exaggerated application rates <LOQ.

TABLE C.4. Summary of Residue Data from Crop Field Trials with Mesotrione.

Matrix	Total Nominal Application Rate (lb ai/A) [kg/ha]	PHI (days)	Residue Levels[1] (ppm) n	Min.	Max.	HAFT[2]	Median	Mean	SD
Mesotrione (PSS + POT)									
Sugarcane	0.318 – 0.360 [0.372 – 0.403]	114	16	<0.01	<0.01	<0.01	<0.01	<0.01	N/A
Mesotrione (PSS + PD)									
Sugarcane	0.325 – 0.348 [0.364 – 0.389]	100	16	<0.01	<0.01	<0.01	<0.01	<0.01	N/A
Mesotrione (POT + PD)									
Sugarcane	0.184 – 0.202 [0.206 – 0.226]	100	16	<0.01	<0.01	<0.01	<0.01	<0.01	N/A
Mesotrione (POT + PD)									
Sugarcane	0.589 [0.659]	100	2	<0.01	<0.01	<0.01	<0.01	<0.01	N/A
Mesotrione (POT + PD)									
Sugarcane	0.932 – 0.985 [1.04 – 1.10]	100	4	<0.01	<0.01	<0.01	<0.01	<0.01	N/A

[1] LOQ = 0.01 ppm for mesotrione.
[2] HAFT = Highest-Average Field Trial.

D. CONCLUSION

The submitted field trial data are adequate and reflect the use of three different applications regimes of the SC formulation of mesotrione at total rates of 0.188 to 0.334 lb ai/A on sugarcane grown in the U.S. with a 100 PHI (PSS+PD or POT+PD treatment regimes) or 114-day PHI (PSS+POT treatment regime). An acceptable method was used for quantitation of residues in/on sugarcane based on untreated control sample spike recoveries.

Sugarcane sample storage intervals between sampling, extraction and analysis ranged from 7 to 13 months. Mesotrione residues were found to be stable in sugarcane under freezer storage conditions for at least 13 months (refer to 47013801.der). Based on these results, residues of mesotrione are expected to be stable in sugarcane over the storage interval of this study.

Residues of mesotrione in sugarcane harvested at 114 days after treatment (PSS+POT) and 100 days after treatment (PSS+PD and POT+PD) were <LOQ (0.01 ppm) in all samples.

For the two decline trials, residues of mesotrione ranged from <0.01 to 5.75 ppm. The only measurable residues occurred for samples harvested at day 0. Decline data show mesotrione residues decrease with increasing PHIs.

Residues of mesotrione in sugarcane harvested at 100 days after being treated at exaggerated application rates (POT+PD) were less than the LOQ (0.01 ppm) in all samples. Additional samples were collected for analysis of sugarcane processed fractions (refined sugar and molasses), but were not analyzed. Residues of mesotrione were <LOQ (<0.01 ppm) in/on all untreated sugarcane samples.

E. REFERENCES

DP#s: 245477 and 260267
Subject: PP#: 8F04954. Mesotrione in/on Field Corn. Evaluation of Residue Data and Analytical Methods. PC Code: 122990. DP Barcodes: D245477, and D260267. Case #: 289589. Submission #s: S541377, and S569871. MRID #s: 44505118, 44505212-23, 44537109-12, 44901719, and 44942401-03.
From: Sarah Levy
To: J.Stone/J.Tompkins
Date: 06-JUN-2001
MRID#: 47136802

DP#: 283827
Subject: Mesotrione. Summary of Analytical Chemistry and Residue Data for Sweet Corn, PP#2F06443, and Response to Data Deficiencies of a Previous HED Review (PP#8F04954, DP Barcodes: D245477 and D260267, 6/6/01, S. Levy).
From: William Cutchin
To: J. Stone/J. Miller
Date: 12-JAN-2005
MRID#: 45651803

DP#: 263245
Subject: Product Chemistry Review of Mesotrione (ZA 1296 Technical (dry)).
From: H. Podall
To: J. Tompkins/J. Stone
Date: 24-FEB-2000
MRID#s: 44373503-44373505, 44505003, 44505004, and 44901701

F. DOCUMENT TRACKING

RDI: G.F. Kramer (05-DEC-2007), RAB1 Chemists (03-OCT-2007)
S. Levy:S10953:PY1:(703)305-0783:7509P:RAB1
Petition #: 6F7162
DP#: 338109
PC Code: 122990

Mesotrione/ZA1296/ PC Code 122990/Sygenta Crop Protection
DACO 7.4.1/7.4.2/OPPTS 860.1500&1520/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial/Residue Decline/Processing Study - Oats

Primary Evaluator: Sarah J. Levy, Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509P)

Date: 05-DEC-2007

Approved by: George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)

Date: 05-DEC-2007

Note: This data-evaluation record (DER) was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 29-JUN-2007). The DER has been reviewed by the HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

MRID#: 47013806. Lin, Kaijun. (2006). Mesotrione: Magnitude of the Residues in or on Oats, Including Processed Commodities. Project Number: T004407-05. Unpublished study prepared by Syngenta Crop Protection, Inc. 225 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection has submitted field trial data for mesotrione on oats. Sixteen field trials were conducted in the U.S. during the 2005 growing season in Regions 1 (NY; 1 trial), 2 (VA; 1 trial), 5 (IA, IL, KS, MI, MN, ND, NE, SD, and WI; 9 trials), 6 (TX; 1 trial), 7 (NE, ND, and SD; 3 trials), and 8 (KS; 1 trial). At each trial location, oats were treated with the 4 lb/gal soluble-concentrate (SC) formulation using one of the following two treatment regimes: (i) a single preemergence soil-surface (PSS) spray at 0.188 lb ai/A (Treatment Regime No. 2); or (ii) a single post-emergence over-the-top (POT) spray applications at 0.094 lb ai/A with the addition of 0.25% (v:v) nonionic surfactant (NIS) (Treatment Regime No. 3).

Preharvest intervals (PHIs) were not applicable for trials treated PSS at planting. Oat forage and hay samples were collected 30 days after the POT application, straw and grain were collected 50 days after application. Additional samples of oat forage and hay were collected at 16, 23, 30, and 37 days after POT to generate residue decline data. At one trial, a single POT application of 4 lb/gal SC was applied to oats at exaggerated rates, for a processing study.

Samples of oat forage, hay, straw, and grain were analyzed for residues of mesotrione using method RAM 366/01 (liquid chromatography with tandem mass-spectrometry detectors (LC-MS/MS)). This method was previously reviewed and forwarded to the U.S. Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual (PAM) Volume II as a confirmatory enforcement method for plant commodities (Memo, W. Cutchin, 12-JAN-2005; DP# 283827). The method is adequate for data collection based on acceptable concurrent recovery data. The validated limit of quantitation (LOQ) was 0.01 ppm for mesotrione in/on oat commodities.

The maximum storage duration of oat samples, from harvest to analysis, was 378 days (12.4 months). The petitioner referenced available storage stability data which demonstrate that mesotrione is stable in corn matrices and soybean seed stored frozen for up to 40-42 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477). The available corn and soybean storage stability data will support the storage conditions and durations of samples from the subject oat field trials.

Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of oat forage, hay, straw, and grain following either a single PSS application of the 4 lb/gal SC formulation made at planting at 0.188 lb ai/A or a single POT spray at 0.094 lb ai/A.

In the residue decline study, residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of oat forage, hay, straw, and grain. Processing samples were not analyzed.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP#: 338109].

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Mesotrione is a triketone herbicide which inhibits the enzyme *p*-hydroxyphenylpyruvate dioxygenase (HPPD), disrupting carotenoid biosynthesis. This process leads to the destruction of chlorophyll, resulting in a bleaching effect in susceptible plants. Mesotrione is intended for preemergence and postemergence use for selective control of annual broadleaf weeds in field, pop, and sweet corn. The nomenclature of mesotrione is summarized in Table A.1, and the physicochemical properties of mesotrione are summarized in Table A.2.

TABLE A.1. Mesotrione Nomenclature.

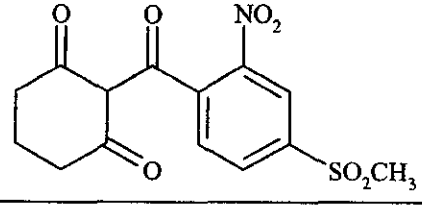
Chemical structure	
Common name	Mesotrione
Company experimental name	ZA1296
IUPAC name	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
CAS name	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
CAS registry number	104206-82-8

TABLE A.1. Mesotrione Nomenclature.	
End-use product (EP)	4 lb/gal SC (Callisto® Herbicide; EPA Reg. No. 100-1131)

TABLE A.2. Physicochemical Properties of Mesotrione.		
Parameter	Value	Reference
Melting range	148.7-152.5°C	RD Memo, H. Podall, 24-FEB-2000; DP#: 263245.
pH	3.4 (1% dispersion in water; 25°C)	
Density	1.46 g/mL, 20°C	
Water solubility	20°C 160 ppm, unbuffered water 0.22 g/100 mL, pH 4.8 1.5 g/100mL, pH 6.9 2.2 g/100 mL, pH 9	
Solvent solubility	20°C 0.37 g/100 mL, methanol 1.7 g/100 mL, ethyl acetate 0.27 g/100 mL, toluene 10.4 g/100 mL, acetonitrile <0.03 g/100 mL, heptane 8.1 g/100 mL, acetone	
Vapor pressure	4.3 x 10^{-8} torr, 20°C	
Dissociation constant, pK_a	3.12, 20°C	
Octanol/water partition coefficient, Log(K_{OW})	20°C log P_{OW} = 0.11 in unbuffered water log P_{OW} = 0.90 in pH 5 buffer log P_{OW} <-1 at pH 7 and 9 buffered water	
UV/visible absorption spectrum	Absorption maximum in methanol at 256 mu, with a molar extinction coefficient of 2.24 x 104 M cm.	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Sixteen field trials were conducted in the United States during the 2005 growing season in Regions 1 (NY; 1 trial), 2 (VA; 1 trial), 5 (IA, IL, KS, MI, MN, ND, NE, SD, and WI; 9 trials), 6 (TX; 1 trial), 7 (NE, ND, and SD; 3 trials), and 8 (KS; 1 trial).

Each trial site consisted of one untreated plot (Treatment Regime No. 1) and two treated plots (Treatment Regimes Nos. 2 and 3). At each trial location, oats were treated with the 4 lb/gal SC formulation using one of the two treatment regimes: (i) a single PSS spray at 0.188 lb ai/A (Treatment Regime No. 2); or (ii) a single POT spray applications at 0.094 lb ai/A with the addition of 0.25% (v:v) nonionic surfactant (Treatment Regime No. 3). The study use pattern is presented in Table B.1.2.

PHIs were not applicable for trials treated PSS at planting. Oat forage and hay samples were collected 30 days after the POT application, straw and grain were collected 50 days after application. Additional samples of oat forage and hay were collected at 16, 23, 30, and 37 days

after POT to generate residue decline data. At one trial, a single POT application of 4 lb/gal SC was applied to oats at exaggerated rates for a processing study.

Oat was grown under normal agricultural conditions. The petitioner reported cultural practices and maintenance pesticides and fertilizers used at each site. Trial site conditions are presented in Table B.1.1. The crop varieties grown are identified in Table C.3. The petitioner included the overall monthly rainfall and temperature ranges for each trial site and stated that actual temperatures and rainfall amounts were within the average historical ranges at all trial sites. Irrigation was used to supplement rainfall as needed.

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State; Year (Trial No.)	Soil characteristics[1]			
	Type	%OM	pH	CEC (meq/g)
Livingston, NY; 2005 (5A-HR-05-6380)	Loam	2.5	6.0	10.8
Suffolk, VA; 2005 (SJ-HR-05-6381)	Sandy Loam	1.4	5.9	3.1
Northwood, ND; 2005 (NN-HR-05-6382)	Loam	6.0	7.1	25.7
Lesterville, SD; 2005 (NF-HR-05-6383)	Loam	3.2	6.2	22.5
Richmond, WI; 2005 (NI-HR-05-6384)	Silty Loam	2.4	6.2	13.2
Geneva, MN; 2005 (NF-HR-05-6385)	Sandy Clay Loam	5.1	5.7	22.4
York, NE; 2005 (NB-HR-05-6386)	Silt Clay Loam	2.8	6.4	19.1
Richland, IA; 2005 (NE-HR-05-6387)	Silt Clay Loam	4.7	6.6	14.4
Sabetha, KS; 2005 (ND-HR-05-6388)	Silt Clay Loam	3.4	7.6	21.0
Conklin, MI; 2005 (NL-HR-05-6389)	Loam	2.2	6.9	8.2
Champaign, IL; 2005 (4A-HR-05-6390)	Clay Loam	3.7	6.3	33.0
Clay, TX; 2005 (SA-HR-05-6391)	Clay	2.2	7.8	46.8
New Rockford, ND; 2005 (NN-HR-05-6392)	Sandy Loam	2.2	7.7	17.0
Frederick, SD; 2005 (NF-HR-05-6393)	Sandy Loam	3.8	6.8	22.2
Grand Island, NE; 2005 (NB-HR-05-6394)	Clay Loam	2.7	6.6	21.8
Larned, KS; 2005 (NM-HR-05-6395)	Silt Loam	2.9	6.7	15.0

[1] OM = organic matter; CEC = cation-exchange capacity.

TABLE B.1.2. Study Use Pattern.

Location City, State; Year (Trial ID)	EP[1]	Application						Tank Mix/ Adjuvants
		Treatment No.[2]	Method; Timing	Volume[3] (GPA)	Rate (lb ai/A)	RTI[4] (days)	Total Rate (lb ai/A)	
Livingston, NY; 2005 (5A-HR-05-6380)	4 lb/gal SC	2	1. PSS; planting	19	0.188	NA	0.188	NA
		3	1. POT; BBCH 59-61	19	0.094	NA	0.094	NIS[5] 0.25% v:v
Suffolk, VA; 2005 (SJ-HR-05-6381)	4 lb/gal SC	2	1. PSS; planting	18	0.188	NA	0.188	NA
		3	1. POT; BBCH 75	18	0.094	NA	0.094	NIS 0.25% v:v
Northwood, ND; 2005 (NN-HR-05-6382)	4 lb/gal SC	2	1. PSS; planting	20	0.188	NA	0.188	NA
		3	1. POT; BBCH 23	15	0.094	NA	0.094	NIS 0.25% v:v

TABLE B.1.2. Study Use Pattern.

Location City, State; Year (Trial ID)	EP[1]	Application						Tank Mix/ Adjuvants
		Treatment No.[2]	Method; Timing	Volume[3] (GPA)	Rate (lb ai/A)	RTI[4] (days)	Total Rate (lb ai/A)	
Lesterville, SD; 2005 (NF-HR-05-6383)	4 lb/gal SC	2	1. PSS; planting	19	0.188	NA	0.188	NA
		3	1. POT; *BBCH 32*	19	0.094	NA	0.094	NIS 0.25% v:v
Richmond, WI; 2005 (NI-HR-05-6384)	4 lb/gal SC	2	1. PSS; planting	18	0.188	NA	0.188	NA
		3	1. POT; late boot to early head	24	0.094	NA	0.094	NIS 0.25% v:v
Geneva, MN; 2005 (NF-HR-05-6385)	4 lb/gal SC	2	1. PSS; planting	17	0.188	NA	0.188	NA
		3	1. POT; BBCH 21	17	0.094	NA	0.094	NIS 0.25% v:v
York, NE; 2005 (NB-HR-05-6386)	4 lb/gal SC	2	1. PSS; planting	20	0.188	NA	0.188	NA
		3	1. POT; BBCH 31	20	0.094	NA	0.094	NIS 0.25% v:v
Richland, IA; 2005 (NE-HR-05-6387)	4 lb/gal SC	2	1. PSS; planting	15	0.188	NA	0.188	NA
		3	1. POT; BBCH 80	16	0.094	NA	0.094	NIS 0.25% v:v
Sabetha, KS; 2005 (ND-HR-05-6388)	4 lb/gal SC	2	1. PSS; planting	14	0.188	NA	0.188	NA
		3	1. POT; tillering *(1-3 tillers)*	14	0.094	NA	0.094	NIS 0.25% v:v
Conklin, MI; 2005 (NL-HR-05-6389)	4 lb/gal SC	2	1. PSS; planting	17	0.188	NA	0.188	NA
		3	1. POT; 5-6 leaves	16	0.094	NA	0.094	NIS 0.25% v:v
Champaign, IL; 2005 (4A-HR-05-6390)	4 lb/gal SC	2	1. PSS; planting	16	0.188	NA	0.188	NA
		3	1. POT; BBCH 26	13	0.094	NA	0.094	NIS 0.25% v:v
		4	1. POT; BBCH 26	13	0.282	NA	0.282	NIS 0.25% v:v
		5	1. POT; BBCH 26	13	0.47	NA	0.47	NIS 0.25% v:v
Clay, TX; 2005 (SA-HR-05-6391)	4 lb/gal SC	2	1. PSS; planting	10	0.188	NA	0.188	NA
		3	1. POT; BBCH 43	11	0.094	NA	0.094	NIS 0.25% v:v
New Rockford, ND; 2005 (NN-HR-05-6392)	4 lb/gal SC	2	1. PSS; planting	20	0.188	NA	0.188	NA
		3	1. POT; BBCH 43	15	0.094	NA	0.094	NIS 0.25% v:v
Frederick, SD; 2005 (NF-HR-05-6393)	4 lb/gal SC	2	1. PSS; planting	15	0.188	NA	0.188	NA
		3	1. POT; BBCH 21-31	15	0.094	NA	0.094	NIS 0.25% v:v
Grand Island, NE; 2005 (NB-HR-05-6394)	4 lb/gal SC	2	1. PSS; planting	20	0.188	NA	0.188	NA
		3	1. POT; BBCH 31	20	0.094	NA	0.094	NIS 0.25% v:v
Larned, KS;	4 lb/gal	2	1. PSS; planting	14	0.188	NA	0.188	NA

TABLE B.1.2. Study Use Pattern.

Location City, State; Year (Trial ID)	EP[1]	Application						Tank Mix/ Adjuvants
		Treatment No.[2]	Method; Timing	Volume[3] (GPA)	Rate (lb ai/A)	RTI[4] (days)	Total Rate (lb ai/A)	
2005 (NM-HR-05-6395)	SC	3	1. POT; tillering (1-2 tillers)	14	0.094	NA	0.094	NIS 0.25% v:v

[1] EP = End-use Product; Callisto ® 4SC Herbicide (EPA Reg. No. 100-1131).
[2] Treatment Regime No. 2 = Single PSS spray made at planting; Treatment Regime No. 3 = Single POT spray; and Treatment Regime Nos. 4 and 5 = Single POT spray at exaggerated rates.
[3] GPA = Gallons per acre.
[4] RTI = Retreatment Interval; NA=not applicable because a single application was made.
[5] NIS = Nonionic surfactant.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Regions	Oats		
	Submitted	Requested	
		Canada	U.S.
1	1		1
2	1		1
5	9		9
6	1		1
7	3		3
8	1		1
Total	16		16

B.2. Sample Handling and Preparation

A single control and duplicate treated oat samples were collected from each trial site. Oat forage and hay samples were collected 30 days after the POT application (~2 lbs each). Oat straw (~2 lbs) and grain (~3 lbs) samples were collected 50 days after the POT application. Additional oat forage and hay samples were collected at 16, 23, 30, and 37 days after POT to generate residue decline data. At one trial treated at exaggerated rates, bulk oat grain samples (~50 lbs) were collected to generate aspirated processed fractions, rolled oats and flour.

All samples were placed in frozen storage at the field sites, and were shipped frozen via Agricultural Chemicals Development Service (ACDS) truck to Syngenta Crop Protection (Greensboro, NC) for residue analysis. Samples were stored frozen (~-15°C) at the analytical laboratory until preparation for extraction/analysis. Samples of forage, hay and straw were prepared by cutting into 2" pieces with meat cleavers or hand shears in the presence of dry ice.

Bulk oat grain samples for processing were delivered fresh to GLP Technologies (Navasota, TX). Grain samples were processed into hull, groats, rolled oats, bran, and flour using simulated commercial processing procedures. After processing all samples were stored frozen prior to shipment to the analytical laboratory.

B.3. Analytical Methodology

Samples of oat commodities were analyzed for residues of mesotrione using LC-MS/MS method, RAM 366/01, entitled "Residue Analytical Method for the Determination of Residues of Mesotrione and 4-(Methylsufonyl)-2-Nitrobenzoic Acid (MNBA) in Crop Samples." A detailed description of the method was not included in the study. This method has been previously reviewed and was forwarded to FDA for inclusion in PAM Vol. II as a confirmatory enforcement method for plant commodities (Memo, W. Cutchin, 12-JAN-2005; DP#: 283827).

Briefly, homogenized samples were mixed with sodium chloride (10:1, wt:wt) and extracted with acetonitrile (ACN):water (1:1, v:v). An aliquot of the extract was diluted with water and the final volume adjusted with 90% water/methanol for LC-MS/MS analysis. The monitored ion transition was m/z 338 → 291. The validated LOQ was 0.01 ppm.

C. RESULTS AND DISCUSSION

Sample storage conditions and durations are summarized in Table C.2. Storage durations of oat samples from harvest to analysis were 56-357 days (1.8-11.7 months) for forage, 56-378 days (1.8-12.4 months) for hay and 32-331 days (1.1-10.9 months) for straw and grain. The petitioner referenced available storage stability data which demonstrate that mesotrione is stable in corn matrices and soybean seed stored frozen for up to 40-42 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477). The available corn and soybean storage stability data will support the storage conditions and durations of samples from the subject oat field trials.

Samples of oat forage, hay, straw, and grain were analyzed for residues of mesotrione using LC-MS/MS method RAM 366/01. This method was previously reviewed and forwarded to FDA for inclusion in PAM Vol. II as a confirmatory enforcement method for plant commodities (Memo, W. Cutchin, 12-JAN-2005; DP#: 283827). The validated LOQ was 0.01 ppm for mesotrione. Concurrent method recoveries were generally within the acceptable range of 70-120% (Table C.1) with some low recoveries: three samples of oat hay and one sample each of oat straw and grain fortified with mesotrione at 0.01 ppm resulted in recoveries at 61-68% and one sample of oat hay fortified with mesotrione at 0.02 ppm resulted in a recovery at 67%. Adequate sample calculations and chromatograms were provided. Apparent residues of mesotrione were below the LOQ in/on 14 untreated samples each of oat forage, hay, straw and in/on 15 samples of untreated grain.

Residue data from the oat field trials are reported in Table C.3. A summary of the residue data for oat forage, hay, straw, and grain is presented in Table C.4. Residues of mesotrione were below the method LOQ (<0.01 ppm) in/on all samples of oats following a single application of either a PSS spray at 0.188 lb ai/A or a POT spray at 0.094 lb ai/A of Callisto 4SC. Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of oat forage, hay, straw, and grain following: (i) a single PSS application of the 4 lb/gal SC formulation at 0.188 lb ai/A (Treatment Regime No. 2); and (ii) a single POT application of the 4 lb/gal SC formulation at 0.094 lb ai/A and harvested at a 30-day PHI for forage and hay and a 50-day PHI for straw and

grain (Treatment Regime No. 3). Mesotrione residues were not found in any of the oat forage, hay, straw, or grain samples treated with exaggerated rates. Processed fractions were not analyzed.

In the residue decline study, residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of oat forage, hay, straw and grain.

TABLE C.1. Summary of Concurrent Recoveries of Mesotrione from Oats.

Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± SD[1] (%)
Oat forage	0.01	14	70, 70, 71, 73, 74, 75, 78, 78, 79, 79, 80, 81, 82, 93	77 ± 6
	0.02	1	74	74
	0.05	6	78, 82, 82, 84, 91, 91	85 ± 5
	0.1	1	86	86
	0.5	1	70	70
	1	1	94	94
	Total	**24**	**70-94**	**80 ± 7**
Oat hay	0.01	12	65, 67, 68, 70, 70, 71, 71, 74, 74, 77, 78, 85	73 ± 5
	0.02	3	67, 71, 74	71 ± 4
	0.05	4	72, 75, 78, 79	76 ± 3
	0.1	3	82, 83, 85	84 ± 1
	0.2	1	86	86
	0.5	1	74	74
	Total	**24**	**65-85**	**75 ± 6**
Oat straw	0.01	11	67, 72, 72, 73, 73, 73, 74, 78, 87, 87, 94	77 ± 8
	0.02	2	80, 86	83
	0.1	1	78	78
	0.5	3	81, 84, 89	85 ± 4
	Total	**17**	**67-94**	**79 ± 8**
Oat grain	0.01	9	61, 70, 71, 71, 72, 75, 77, 77, 84	72 ± 5
	0.02	1	70	70
	0.05	5	78, 79, 80, 80, 85	81 ± 3
	0.2	1	84	84
	1	1	91	91
	Total	**17**	**61-91**	**77 ± 7**

[1] Standard deviation is applicable only for groups ≥ 3 samples.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability[2]
Oat forage	< -15	56-357 days (1.8-11.7 months)	Residues of mesotrione are relatively stable in/on fortified grain matrices (forage, stover and grain) stored frozen for 40-42 months.
Oat hay		56-378 days (1.8-12.4 months)	
Oat straw		32-331 days (1.1-10.9 months)	
Oat grain		32-331 days (1.1-10.9 months)	

[1] Duration from harvest to analysis. All samples were analyzed within 8 days of extraction.
[2] Refer to Memo, S. Levy, 06-JUN-2001; DP#: 245477.

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial No.)	Region	Crop; Variety	Commodity or Matrix	Total Rate (lb ai/A)	PHI (days)	Mesotrione Residues (ppm)
Treatment Regime No. 2: Single PSS spray made at planting						
Livingston, NY; 2005 (5A-HR-05-6380)	1	Oat; Armor	Forage	0.188	NA	<0.01, <0.01
			Hay		70	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Suffolk, VA; 2005 (SJ-HR-05-6381)	2	Oat; Coker	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Northwood, ND; 2005 (NN-HR-05-6382)	5	Oat; Morton	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Lesterville, SD; 2005 (NF-HR-05-6383)	5	Oat; Jerry	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Richmond, WI; 2005 (NI-HR-05-6384)	5	Oat; Esker	Forage	0.188 (PSS)	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial No.)	Region	Crop; Variety	Commodity or Matrix	Total Rate (lb ai/A)	PHI (days)	Mesotrione Residues (ppm)
Geneva, MN; 2005 (NF-HR-05-6385)	5	Oat; Drumlin	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
York, NE; 2005 (NB-HR-05-6386)	5	Oat; Jerry	Forage	0.188	NA	<0.01, <0.01
					16	<0.01, <0.01
					23	<0.01, <0.01
					30	<0.01, <0.01
					37	<0.01, <0.01
			Hay		NA	<0.01, <0.01
					16	<0.01, <0.01
					23	<0.01, <0.01
					30	<0.01, <0.01
					37	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Richland, IA; 2005 (NE-HR-05-6387)	5	Oat; Jerry	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Sabetha, KS; 2005 (ND-HR-05-6388)	5	Oat; Loyal	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Conklin, MI; 2005 (NL-HR-05-6389)	5	Oat; Prairie	Forage	0.188	NA	<0.01, <0.01
					16	<0.01, <0.01
					23	<0.01, <0.01
					30	<0.01, <0.01
					37	<0.01, <0.01
			Hay		NA	<0.01, <0.01
					16	<0.01, <0.01
					23	<0.01, <0.01
					30	<0.01, <0.01
					37	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Champaign, IL; 2005 (4A-HR-05-6390)	5	Oat; VHS	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Clay, TX; 2005	6	Oat; La-604	Forage	0.188	NA	<0.01, <0.01

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial No.)	Region	Crop; Variety	Commodity or Matrix	Total Rate (lb ai/A)	PHI (days)	Mesotrione Residues (ppm)
(SA-HR-05-6391)			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
New Rockford, ND; 2005 (NN-HR-05-6392)	7	Oat; Morton	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Frederick, SD; 2005 (NF-HR-05-6393)	7	Oat; Reeves	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Grand Island, NE; 2005 (NB-HR-05-6394)	7	Oat; Jerry	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Larned, KS; 2005 (NM-HR-05-6395)	8	Oat; Loyal	Forage	0.188	NA	<0.01, <0.01
			Hay		NA	<0.01, <0.01
			Straw		NA	<0.01, <0.01
			Grain		NA	<0.01, <0.01
Treatment Regime No. 3: Single POT spray						
Livingston, NY; 2005 (5A-HR-05-6380)	1	Oats; Armor	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Suffolk, VA; 2005 (SJ-HR-05-6381)	2	Oat; Coker	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Northwood, ND; 2005 (NN-HR-05-6382)	5	Oat; Morton	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Lesterville, SD; 2005 (NF-HR-05-6383)	5	Oat; Jerry	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Richmond, WI; 2005 (NI-HR-05-6384)	5	Oat; Esker	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Geneva, MN; 2005 (NF-HR-05-6385)	5	Oat; Drumlin	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial No.)	Region	Crop; Variety	Commodity or Matrix	Total Rate (lb ai/A)	PHI (days)	Mesotrione Residues (ppm)
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
York, NE; 2005 (NB-HR-05-6386)	5	Oat; Jerry	Forage	0.094	16	<0.01, <0.01
					23	<0.01, <0.01
					30	<0.01, <0.01
					37	<0.01, <0.01
			Hay		16	<0.01, <0.01
					23	<0.01, <0.01
					30	<0.01, <0.01
					37	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Richland, IA; 2005 (NE-HR-05-6387)	5	Oat; Jerry	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Sabetha, KS; 2005 (ND-HR-05-6388)	5	Oat; Loyal	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Conklin, MI; 2005 (NL-HR-05-6389)	5	Oat; Prairie	Forage	0.094	16	<0.01, <0.01
					23	<0.01, <0.01
					30	<0.01, <0.01
					37	<0.01, <0.01
			Hay		16	<0.01, <0.01
					23	<0.01, <0.01
					30	<0.01, <0.01
					37	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Champaign, IL; 2005 (4A-HR-05-6390)	5	Oat; VHS	Forage	0.094	30	<0.01, <0.01
				0.282	30	<0.01, <0.01
				0.47	30	<0.01, <0.01
			Hay	0.094	30	<0.01, <0.01
				0.282	30	<0.01, <0.01
				0.47	30	<0.01, <0.01
			Straw	0.094	50	<0.01, <0.01
				0.282	50	<0.01, <0.01
				0.47	50	<0.01, <0.01
			Grain	0.094	50	<0.01, <0.01
				0.282	50	<0.01, <0.01
				0.47	50	<0.01, <0.01

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; Year (Trial No.)	Region	Crop; Variety	Commodity or Matrix	Total Rate (lb ai/A)	PHI (days)	Mesotrione Residues (ppm)
Clay, TX; 2005 (SA-HR-05-6391)	6	Oat; La-604	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
New Rockford, ND; 2005 (NN-HR-05-6392)	7	Oat; Morton	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Frederick, SD; 2005 (NF-HR-05-6393)	7	Oat; Reeves	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Grand Island, NE; 2005 (NB-HR-05-6394)	7	Oat; Jerry	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01
Larned, KS; 2005 (NM-HR-05-6395)	8	Oat; Loyal	Forage	0.094	30	<0.01, <0.01
			Hay		30	<0.01, <0.01
			Straw		50	<0.01, <0.01
			Grain		50	<0.01, <0.01

TABLE C.4. Summary of Residue Data from Crop Field Trials with Mesotrione.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT[1]	Median	Mean	SD
Treatment Regime No. 2: Single PSS spray made at planting									
Oat forage	0.188	NA	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat hay		NA	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat straw		NA	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat grain		NA	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Treatment Regime No. 3: Single POT spray									
Oat forage	0.094	30	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat hay		30	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat straw		50	32	<0.01	<0.01	<0.01	<0.01	<0.01	--
Oat grain		50	32	<0.01	<0.01	<0.01	<0.01	<0.01	--

[1] HAFT = Highest-Average Field Trial.

D. CONCLUSION

The submitted field trial data are acceptable and reflect a single application of the 4 lb/gal SC formulation either by a PSS spray at 0.188 lb ai/A at planting or a POT spray with addition of 0.25% (v:v) NIS at 0.094 lb ai/A. An acceptable method was used for quantitation of residues

in/on oat commodities, and adequate data are available to support sample storage durations and conditions.

Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of oat forage, hay, straw, and grain following either a single PSS application of the 4 lb/gal SC formulation made at planting at 0.188 lb ai/A or a single POT spray at 0.094 lb ai/A. In the residue decline study, residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of oat forage, hay, straw, and grain. Residues of mesotrione were below the LOQ (<0.01 ppm) in/on all samples of oat treated at an exaggerated rates. Processing samples were not analyzed.

E. REFERENCES

DP#: 263245
Subject: Product Chemistry Review of Mesotrione (ZA 1296 Technical (dry)).
From: H. Podall
To: J. Tompkins/J. Stone
Date: 2/24/00
MRIDs: 44373503-44373505, 44505003, 44505004, and 44901701

DP#s: 245477 and 260267
Subject: PP#: 8F04954. Mesotrione in/on Field Corn. Evaluation of Residue Data and Analytical Methods. PC Code: 122990.
From: S. Levy
To: J. Stone/ J. Tompkins
Dated: 6/6/01
MRIDs: 44505118, 44505212-23, 44537109-12, 44901719, and 44942401-03

DP#: 283827
Subject: Mesotrione. Summary of Analytical Chemistry and Residue Data for Sweet Corn, PP#2F06443, and Response to Data Deficiencies of a Previous HED Review (PP#8F04954, DP Barcodes: D245477 and D260267, 6/6/01, S. Levy).
From: W. Cutchin
To: J. Stone/ J. Miller
Dated: 1/12/05
MRIDs: 45651801-45651803, 45651813, 45651814, 45651816, 45651817, and 45665901

F. DOCUMENT TRACKING

RDI: G.F. Kramer (05-DEC-2007), RAB1 Chemists (26-SEP-2007)
S. Levy:S10953:PY1:(703)305-0783:7509P:RAB1
Petition #: 6F7162
DP#: 338109
PC Code: 122990

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Mesotrione/ZA01296/PC Code 122990)Syngenta Crop Protection, Inc.
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial/Residue Decline – Rhubarb

Primary Evaluator: Date: 05-DEC-2007
Sarah J. Levy, Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509P)

Approved by: Date: 05-DEC-2007
George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)

Note: This data-evaluation record (DER) was originally prepared by Tetrahedron, Inc, subcontractor for Versar, Inc. (6850 Versar Center, Springfield, VA 22151; submitted 31-MAY-2007). The DER has been reviewed by the HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORTS:

MRID#: 47013807. Lin, K. (2006). Mesotrione - Magnitude of the Residues in or on Rhubarb. Lab Project Number: T014372-05. Unpublished study prepared by Syngenta Crop Protection, Inc. 65 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted field trial data for mesotrione in/on rhubarb. Four field trials (three harvest and one decline) were conducted in the U.S. encompassing Regions 5 (1 trial in Illinois and 1 trial in Michigan), and 12 (1 trial in Oregon and 1 trial in Washington) during the 2006 growing season. At each trial location, there was one untreated and two treated plots.

The treated plots were treated with Callisto® 4SC (a 4 lbs ai/gal soluble-concentrate formulation), using one of the following two regimes: by one time pre-emergence soil-surface (PSS) spray at a rate of (1) 0.180-0.194 lbs ai/A (~211 g ai/ha) or (2) 0.301-0.313 lbs ai/A (~336 g ai/ha). Applications were made using a backpack sprayer at a volume of 16.5-30.3 gallons per acre (GPA) (154-284 L/ha). An adjuvant was not added to the spray formulations.

For each of the field trials, a single untreated and duplicate treated samples of mature rhubarb were harvested by hand 42 days following the last test substance application (42-day pre-harvest interval (PHI)). At the Illinois site (4A-HR-06-7165), one control and duplicate treated samples were harvested at 28, 35, 42, and 49 days after the last application to determine residue decline.

Rhubarb samples were analyzed for residues of mesotrione using method RAM 366/01 (liquid chromatography with tandem mass-spectrometry detectors (LC-MS/MS)), with modifications. This method was previously reviewed and forwarded to the U.S. Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual (PAM) Volume II as a confirmatory enforcement method for plant commodities (Memo, W. Cutchin, 12-JAN-2005; DP#: 283827). The method was adequate for data collection based on acceptable concurrent method recoveries. The validated limit of quantitation (LOQ) was 0.01 ppm for mesotrione in/on rhubarb.

Rhubarb samples were stored frozen prior to analysis; the maximum storage interval from harvest to extraction was 5 months. No storage stability data are available for rhubarb (a

member of the leafy vegetable group); however, residues of mesotrione are stable in/on blueberry, asparagus, sugarcane, and okra stored frozen at <-15°C for 13 months (47013801.der, in preparation). Additionally, residues of mesotrione were found to be stable in corn grain, corn forage, corn fodder, soybean seed, and radish root for up to 40 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477). Adequate storage stability data are available to support the storage conditions and intervals of samples from the rhubarb trials.

Residues of mesotrione treated by PSS spray rates of ~0.188 and ~0.3 lbs ai/A and harvested 42 days after application were less than the LOQ (0.01 ppm) in most samples. All but one sample of the residue decline data were less than the LOQ (0.01 ppm). The measurable sample (0.011 ppm) occurred on the 28 PHI at the ~0.3 lbs ai/A application rate. Analysis of untreated control samples demonstrated that they were less then the limit of detection (LOD) of 0.01 ppm.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable, pending submission of storage stability data to support the storage conditions of rhubarb.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP#: 338109].

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The following deviations from regulatory requirements were reported: (1) Weather data were not collected according to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)-GLP requirements; National Oceanic and Atmospheric Administration (NOAA) weather data were reported; (2) Tank mix storage stability data were not generated as required in 40 CFR 160.113(a)(3); (3) Maintenance chemicals and irrigation were not applied under GLP; and, (4) Soil characterization analysis was not conducted under GLP. These deviations did not impact the validity of the study.

A. BACKGROUND INFORMATION

Mesotrione is a triketone herbicide which inhibits the enzyme *p*-hydroxyphenylpyruvate dioxygenase (HPPD), disrupting carotenoid biosynthesis. This process leads to the destruction of chlorophyll, resulting in a bleaching effect in susceptible plants. Mesotrione is intended for preemergence and postemergence use for selective control of annual broadleaf weeds in field, pop, and sweet corn. The nomenclature of mesotrione is summarized in Table A.1, and the physicochemical properties of mesotrione are summarized in Table A.2.

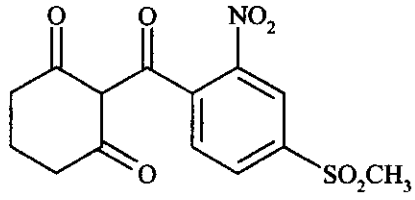
TABLE A.1. Mesotrione Nomenclature.	
Chemical structure	
Common name	Mesotrione
Company experimental name	ZA01296
IUPAC name	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
CAS name	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
CAS registry number	104206-82-8
End-use product (EP)	4 lb/gal SC (Callisto® Herbicide; EPA Reg. No. 100-1131)

TABLE A.2. Physicochemical Properties of Mesotrione.		
Parameter	Value	Reference
Melting range	148.7-152.5°C	RD Memo, H. Podall, 24-FEB-2000; DP#: 263245.
pH	3.4 (1% dispersion in water; 25°C)	
Density	1.46 g/mL, 20°C	
Water solubility	20°C 160 ppm, unbuffered water 0.22 g/100 mL, pH 4.8 1.5 g/100mL, pH 6.9 2.2 g/100 mL, pH 9	
Solvent solubility	20°C 0.37 g/100 mL, methanol 1.7 g/100 mL, ethyl acetate 0.27 g/100 mL, toluene 10.4 g/100 mL, acetonitrile <0.03 g/100 mL, heptane 8.1 g/100 mL, acetone	
Vapor pressure	4.3 x 10^{-8} torr, 20°C	
Dissociation constant, pK_a	3.12, 20°C	
Octanol/water partition coefficient, Log(K_{OW})	20°C log P_{OW} = 0.11 in unbuffered water log P_{OW} = 0.90 in pH 5 buffer log P_{OW} <-1 at pH 7 and 9 buffered water	
UV/visible absorption spectrum	Absorption maximum in methanol at 256 mu, with a molar extinction coefficient of 2.24 x 10^4 M cm.	

B. EXPERIMENTAL DESIGN

Rhubarb was grown under normal agricultural conditions in trial plots at each of the field trials. The control plots were separated sufficiently to exclude any contamination from the treated plots.

The rhubarb plants at all four trial sites were treated with Callisto® 4SC, a formulation of mesotrione, using one of the following two regimes: (1) 0.180-0.194 lbs ai/A (~211 g ai/ha) or (2) 0.301-0.313 lbs ai/A (~336 g ai/ha). Applications were made using a backpack sprayer at a

volume of 16.5-30.3 GPA (154-284 L/ha). An adjuvant was not added to the spray formulations.

Single untreated and duplicate treated samples of mature rhubarb were harvested by hand at 42 days following the last test substance application (42-day PHI). In addition, at one of the sites (4A-HR-06-7165), one control and duplicate treated samples were also harvested at 28, 35, 42, and 49 days after the last application to determine residue decline. Samples were collected from the control plot first and then from the treated plot, avoiding the plot boundaries and row ends.

At least 2.5 pounds of RAC samples were collected (12 rhubarb petioles were collected from 6 separate plants, 2 from each plant). Duplicate samples were taken from each treated plot.

After collection, rhubarb petioles samples were stored frozen, and shipped frozen to Syngenta's Greensboro, NC facility via Agricultural Chemicals Development Service (ACDS).

Cultivation and trial maintenance methods were conducted in accordance with local agricultural practices; maintenance chemicals used at each trial site during the study were reported. Average monthly minimum and maximum temperatures, and total monthly precipitation amounts were reported for each trial from planting to harvest. According to the Study Report, temperature and precipitation were generally typical at each site as compared to historical 10-year data. The historical data were only reported for precipitation. No unusual weather conditions occurred during the study except for more than normal rainfall for March at one site: 4H-HR-06-7165. Supplementary irrigation was not used at the sites.

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State, EPA Region; Year (Trial No.)	Soil characteristics[1]				Meteorological Data	
	Type	%OM	pH	CEC (meq/g)	Overall Monthly Rainfall Range (inches)	Overall Monthly Temperature Range (°F)
Cobden, IL, Region 5; 2006 (4A-HR-06-7165)	Silt Loam	5.0	6.7	15.0	3.5 - 9.2	25 -93
Comstock Park, MI, Region 5; 2006 (NL-HR-06-7166)	Loamy Sand	1.3	6.7	4.2	2.2 – 4.9	26 – 91
Hillsboro, OR, Region 12; 2006 (WF-HR-06-7167)	Loam	3.4	6.9	20.4	2.6 – 5.1	27 – 83
Vancouver, WA, Region 12; 2006 (WF-HR-06-7168)	Sandy Loam	3.8	5.8	15.2	2.5 - 4.4	13 - 73

[1] OM = organic matter; CEC = cation-exchange capacity.

TABLE B.1.2. Study Use Pattern.

Trial Identification: City, State, EPA Region; Year (Trial No.)	EP[1]	Application						
		Application Method/ Timing	Growth Stage	Volume[2] GPA [L/ha]	Rate (lb ai/A) [g ai/ha]	RTI[3] (days)	Total Rate (lb ai/A) [g ai/ha]	Tank Mix Adjuvants
Cobden, IL, Region 5; 2006 (4A-HR-06-7165)	Callisto 4.0 SC	1. PSS	0	16.5 [154]	0.180 [201]	NA	0.180 [201]	NA
		2. PSS	0	18.0 [168]	0.313 [350]	NA	0.313 [350]	NA
Comstock Park, MI, Region 5; 2006 (NL-HR-06-7166)	Callisto 4.0 SC	1. PSS	Pre-emergence	25.8 [241]	0.189 [211]	NA	0.189 [211]	NA
		2. PSS	Pre-emergence	26.0 [243]	0.304 [340]	NA	0.304 [340]	NA
Hillsboro, OR, Region 12; 2006 (WF-HR-06-7167)	Callisto 4.0 SC	1. PSS	Dormant	16.8 [157]	0.187 [210]	NA	0.187 [210]	NA
		2. PSS	Dormant	17.1 [160]	0.306 [343]	NA	0.306 [343]	NA
Vancouver, WA, Region 12; 2006 (WF-HR-06-7168)	Callisto 4.0 SC	1. PSS	08	30.3 [284]	0.194 [217]	NA	0.194 [217]	NA
		2. PSS	08	29.8 [278]	0.301 [337]	NA	0.301 [337]	NA

[1] EP = End-use Product.
[2] GPA = gallons per acre.
[3] Retreatment interval.
PSS = Preemergence soil surface spray.
NA = Not Applicable.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Regions	Rhubarb		
	Submitted	Requested*	
		Canada	U.S.
5	2		
12	2		
Total	4		

* OPPTS 860.1500 requires a minimum of two trials for rhubarb, but does not indicate specific regions for the trials.

B.2. Sample Handling and Preparation

After collection, rhubarb petiole samples were stored frozen at the field site. Samples remained frozen at the field site until shipment to Syngenta, Greensboro, NC via Agricultural Chemicals Development Service (ACDS) freezer truck. Samples were kept under frozen conditions at the laboratory (<-15°C) until further preparation, extraction, and analysis. Rhubarb petioles were cut into approximately two-inch pieces with hand shears. Composited samples were ground in a food cutter. Dry ice was used as necessary to keep the sample frozen. After preparation, samples were place in labeled double polyethylene bags and stored frozen at <-15°C until analyzed.

B.3. Analytical Methodology

Rhubarb samples were analyzed for residues of mesotrione using Method RAM 366/01 with modifications as follows: a 10-gram sub-sample was Polytron-homogenized for 3-5 minutes with 100 mL of 50% ACN/H_2O (acetonitrile/water) after addition of one gram of sodium chloride (NaCl). Approximately 40 mL of the mixture was centrifuged and an aliquot was taken from the supernatant and diluted with water. The final volume was adjusted with 90% H_2O/methanol

(MeOH). The sample final solution was injected onto a LC-MS/MS system for residue analysis. The LOQ was 0.01 ppm for mesotrione for rhubarb.

C. RESULTS AND DISCUSSION

Sample storage conditions and intervals are summarized in Table C.2. The maximum storage interval of rhubarb samples, from harvest to extraction, was 157 days (5 months). Samples were stored frozen at the field sites for 1-20 days; however temperatures at field sites were not provided. Samples were shipped frozen from the field site to the laboratory, taking anywhere from 1-16 days from date of shipment to date of receipt. Again, temperatures during transit were not reported. Storage intervals between sampling, extraction and analysis ranged from 4 to 5 months. Storage stability data are not available for rhubarb (a member of the leafy vegetable group); however, residues of mesotrione are stable in/on blueberry, asparagus, sugarcane, and okra stored frozen at <-15°C for 13 months (47013801.der, in preparation). Additionally, residues of mesotrione were found to be stable in corn grain, corn forage, corn fodder, soybean seed, and radish root for up to 40 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477).

Rhubarb samples were analyzed for residues of mesotrione using modified Method RAM 366/01 with modifications. The samples were analyzed within 2 days of extraction. The validated LOQ was 0.01 ppm for mesotrione in rhubarb. Method validation results, apart from concurrent procedural recoveries, were not provided for the method used in this study. Concurrent method recoveries are reported in Table C.1. Concurrent recoveries from controls fortified with mesotrione at 0.01 to 1.0 ppm ranged from 71.8% to 97.9% (average of 88.4% with a standard deviation of 7.6%, n=14). The average recoveries for mesotrione were in the generally accepted range of 70% to 120%. The fortification levels encompassed the expected residues in rhubarb. The method was adequate for data collection based on acceptable concurrent method recoveries.

Residue data from the rhubarb field trials are reported in Table C.3. A summary of the residue data for rhubarb from the 42-day PHI is presented in Table C.4. Residues of mesotrione treated by PSS spray rates of ~0.188 and ~0.3 lbs ai/A and harvested 42 days after application were less than the LOQ (0.01 ppm) in all samples. All but one sample of the residue decline data were less than the LOQ (0.01 ppm). The measurable sample (0.011 ppm) occurred on the 28 PHI at the ~0.3 lbs ai/A application rate.

TABLE C.1. Summary of Concurrent Recoveries of Mesotrione from Rhubarb.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± SD* (%)	Overall Mean ± SD (%)
Mesotrione					
Rhubarb petioles	0.01	7	71.8, 83.9, 85.5, 91.6, 91.9, 92.8, 97.9	87.9 ± 8.5	88.4 ± 7.6 %
	0.10	5	75.1, 83.9, 90.5, 91.0, 91.7	86.4 ± 7.1	
	1.0	2	94.8, 95.2	95.0	

* Standard deviations for mean values were not calculated where the number of individual values used to calculate the mean was less than three.

TABLE C.2. Summary of Storage Conditions.

Matrix (RAC)	Analyte	Storage Temperature (°C)	Actual Storage Duration (months)	Interval of Demonstrated Storage Stability* (months)
Rhubarb	Mesotrione	<-15°C (lab)	4 - 5	13

* Storage stability demonstrated in/on blueberry, asparagus, sugarcane and okra (47013801.der, in preparation).

TABLE C.3. Residue Data from Crop Field Trials with Mesotrione.

Trial Identification: City, State; NAFTA Region; Year (Trial No.)	Rhubarb Variety	Commodity	Application Method	Total Rate (lb ai/A) [g ai/ha]	PHI (days)	Uncorrected Residue Value (ppm)
Cobden, IL, Region 5; 2006 (4A-HR-06-7165)	Unknown	Petioles/stems	PSS	0.180 [201]	28	<0.01, <0.01
					35	<0.01, <0.01
					42	<0.01, <0.01
					49	<0.01, <0.01
			PSS	0.313 [350]	28	0.011, <0.01
					35	<0.01, <0.01
					42	<0.01, <0.01
					49	<0.01, <0.01
Comstock Park, MI, Region 5; 2006 (NL-HR-05-7166	McDonald	Petioles/stems	PSS	0.189 [211]	42	<0.01, <0.01
			PSS	0.304 [340]	42	<0.01, <0.01
Hillsboro, OR, Region 12; 2006 (WF-HR-06-7167)	Crimson	Petioles/stems	PSS	0.187 [210]	42	<0.01, <0.01
			PSS	0.306 [343]	42	<0.01, <0.01
Vancouver, WA, Region 12; 2006 (WF-HR-06-7168)	Ruby Red	Petioles/stems	PSS	0.194 [217]	42	<0.01, <0.01
			PSS	0.301 [337]	42	<0.01, <0.01

LOQ = 0.01 ppm for mesotrione.
Residues between the LOD and LOQ were presented as <LOQ in the Study Report.

TABLE C.4. Summary of Residue Data from Crop Field Trials with Mesotrione.

Matrix	Total Application Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels[1] (ppm)						
			n	Min.	Max.	HAFT[2]	Median	Mean	SD
Mesotrione (1. PSS)									
Rhubarb	0.180 – 0.194 [0.201 – 0.217]	42	8	<0.01	<0.01	NA	NA	NA	NA
Mesotrione (2. PSS)									
Rhubarb	0.301 – 0.313 [0.337 – 0.350]	42	8	<0.01	<0.01	NA	NA	NA	NA

[1] LOQ = 0.01 ppm for mesotrione.
[2] HAFT = Highest-Average Field Trial.

D. CONCLUSION

The submitted field trial data are adequate and reflect the use of PSS spray applications of the Callisto® 4SC formulation of mesotrione at total rates of 0.180-0.194 lbs ai/A to 0.301-0.313 lbs ai/A on rhubarb grown in the United States with a 42-day PHI. An acceptable method was used for quantitation of residues in/on rhubarb based on untreated control sample spike recoveries.

Rhubarb samples were stored frozen prior to analysis; the maximum storage interval from harvest to extraction was 5 months. No storage stability data are available for rhubarb (a member of the leafy vegetable group); however, residues of mesotrione are stable in/on blueberry, asparagus, sugarcane, and okra stored frozen at <-15°C for 13 months (47013801.der, in preparation). Additionally, residues of mesotrione were found to be stable in corn grain, corn forage, corn fodder, soybean seed, and radish root for up to 40 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477). Adequate storage stability data are available to support the storage conditions and intervals of samples from the rhubarb trials.

Residues of mesotrione treated by PSS spray rates of ~0.188 and ~0.3 lbs ai/A and harvested 42 days after application were less than the LOQ (0.01 ppm) in all samples. All but one sample of the residue decline data were less than the LOQ (0.01 ppm). The measurable sample (0.011 ppm) occurred on the 28 PHI at the ~0.3 lbs ai/A application rate. Analysis of untreated control samples demonstrated that they were less then the LOQ (0.01 ppm).

E. REFERENCES

DP#s: 245477 and 260267
Subject: PP#: 8F04954. Mesotrione in/on Field Corn. Evaluation of Residue Data and Analytical Methods. PC Code: 122990. DP Barcodes: D245477, and D260267. Case #: 289589. Submission #s: S541377, and S569871. MRID #s: 44505118, 44505212-23, 44537109-12, 44901719, and 44942401-03.
From: Sarah Levy
To: Jim Stone/Jim Tompkins
Date: 06-JUN-2001
MRID#: 47136802

DP#: 283827
Subject: Mesotrione. Summary of Analytical Chemistry and Residue Data for Sweet Corn, PP#2F06443, and Response to Data Deficiencies of a Previous HED Review (PP#8F04954, DP Barcodes: D245477 and D260267, 6/6/01, S. Levy).
From: William Cutchin
To: J. Stone/J. Miller
Date: 12-JAN-2005
MRID#: 45651803

DP#: 263245
Subject: Product Chemistry Review of Mesotrione (ZA 1296 Technical (dry)).
From: H. Podall
To: J. Tompkins/J. Stone
Date: 24-FEB-2000
MRID#s: 44373503-44373505, 44505003, 44505004, and 44901701

F. DOCUMENT TRACKING

RDI: G.F. Kramer (05-DEC-2007), RAB1 Chemists (26-SEP-2007
S. Levy:S10953:PY1:(703)305-0783:7509P:RAB1
Petition #: 6F7162
DP#: 338109
PC Code: 122990

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